UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2018

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

Commission file number: 001-36815

Ascendis Pharma A/S
(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)

The Kingdom of Denmark
(Jurisdiction of incorporation or organization)

Tuborg Boulevard 12
DK-2900 Hellerup, Denmark
(Address of principal executive offices)

Jan Møller Mikkelsen
President and Chief Executive Officer
Tuborg Boulevard 12
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Telephone: +45 70 22 22 44
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
American Depositary Shares, each representing one ordinary share, nominal value DKK 1 per share	**The Nasdaq Stock Market LLC**
Ordinary shares, nominal value DKK 1 per share*	**The Nasdaq Stock Market LLC***

* Not for trading, but only in connection with the registration of the American Depositary Shares.

Securities registered or to be registered pursuant to Section 12(g) of the Act: **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report:

42,135,448 ordinary shares
(as of December 31, 2018)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☒ Yes ☐ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised accounting standards provided pursuant to section 13(a) of the Exchange Act. ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow: ☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

TABLE OF CONTENTS

General

As used herein, references to “we”, “us”, the “company”, “Ascendis”, or “Ascendis Pharma”, or similar terms in this Annual Report on Form 20-F shall mean Ascendis Pharma A/S and, as the context requires, its subsidiaries.

Our consolidated financial statements are presented in euros except where otherwise indicated, and are prepared in accordance with International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standards Board (“IASB”). All references in this annual report to “Dollars” and “$” are to U.S. Dollars, and all references to “euro” or “€” are to European Union euro. Throughout this annual report, references to ADSs mean ADSs or ordinary shares represented by ADSs, as the case may be.

Special Note Regarding Forward-Looking Statements

This annual report contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would,” and other similar expressions that are predictions or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our ongoing phase 3 pediatric studies of TransCon Growth Hormone, or hGH, our ongoing phase 2 study of TransCon Parathyroid Hormone, or PTH, and our plans to initiate a phase 2 study of TransCon C-Type Natriuretic Peptide, or CNP;
- our intention to pursue oncology as our second of three independent therapeutic areas of focus, our receipt of future milestone or royalty payments from our collaboration partners, and the expected timing of such payments;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- our expectations regarding the potential advantages of our product candidates over existing therapies;
- our ability to enter into new collaborations;
- our expectations with regard to the ability to develop additional product candidates using our TransCon technologies and file Investigational New Drug Applications, or INDs, or equivalents for such product candidates;
- our expectations with regard to the ability to seek expedited regulatory approval pathways for our product candidates, including the potential ability to rely on the parent drug’s clinical and safety data with regard to our product candidates;
- our expectations with regard to our current and future collaboration partners to pursue the development of our product candidates and file INDs or equivalents for such product candidates;
- our development plans with respect to our product candidates;
- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;
- the timing or likelihood of regulatory filings and approvals for our product candidates;
- the commercialization of our product candidates, if approved;

- our commercialization, marketing and manufacturing capabilities of our product candidates and associated devices;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our financial performance; and
- developments and projections relating to our competitors and our industry.

These forward-looking statements are based on senior management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this annual report may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section of this annual report titled "Item 3.D—Risk Factors" and elsewhere in this annual report. You are urged to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this annual report. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. Given these risks and uncertainties, you are cautioned not to rely on such forward-looking statements as predictions of future events.

You should read this annual report and the documents that we reference in this annual report and have filed as exhibits to this annual report completely and with the understanding that our actual future results may be materially different from what we expect. You should also review the factors and risks we describe in the reports we will file or submit from time to time with the SEC after the date of this annual report. We qualify all of our forward-looking statements by these cautionary statements.

PART I

Item 1 *Identity of Directors, Senior Management and Advisers*

Not applicable.

Item 2 *Offer Statistics and Expected Timetable*

Not applicable.

Item 3 Key Information

A. Selected Financial Data

The selected consolidated financial data as of December 31, 2018 and 2017 and for each of the years ended December 31, 2018, 2017 and 2016 have been derived from our audited consolidated financial statements and notes thereto set forth in Item 18 of this annual report. The selected consolidated financial data for the years ended December 31, 2015 and 2014 are derived from the audited consolidated financial statements not appearing in this annual report.

The following selected consolidated financial data should be read in conjunction with our "Operating and Financial Review and Prospects" and our consolidated financial statements and related notes appearing elsewhere in this annual report. Our financial statements are prepared in accordance with IFRS.

(EUR'000, except share and per share data)	Years Ended December 31, 2018	2017	2016	2015	2014
Revenue	10,581	1,530	4,606	8,118	13,983
Research and development costs	(140,281)	(99,589)	(66,022)	(40,528)	(19,698)
General and administrative expenses	(25,057)	(13,482)	(11,504)	(9,415)	(6,274)
Operating profit / (loss)	**(154,757)**	**(111,541)**	**(72,920)**	**(41,825)**	**(11,989)**
Share of profit / (loss) in associate	(321)	—	—	—	—
Finance income	24,714	923	7,300	11,048	1,877
Finance expenses	(127)	(13,756)	(3,112)	(2,797)	(228)
Profit / (loss) before tax	**(130,491)**	**(124,374)**	**(68,732)**	**(33,574)**	**(10,340)**
Tax on profit / (loss) for the year	394	477	227	652	682
Net profit / (loss) for the year	**(130,097)**	**(123,897)**	**(68,505)**	**(32,922)**	**(9,658)**
Other comprehensive income / (loss)					
Items that may be reclassified subsequently to profit or loss:					
Exchange differences on translating foreign operations	17	65	6	(14)	(14)
Other comprehensive income / (loss) for the year, net of tax	**17**	**65**	**6**	**(14)**	**(14)**
Total comprehensive income / (loss) for the year, net of tax	**(130,080)**	**(123,832)**	**(68,499)**	**(32,936)**	**(9,672)**
Profit / (loss) for the year attributable to owners of the Company	(130,097)	(123,897)	(68,505)	(32,922)	(9,658)
Total comprehensive income / (loss) for the year attributable to owners of the Company	(130,080)	(123,832)	(68,499)	(32,936)	(9,672)
	EUR	EUR	EUR	EUR	EUR
Basic and diluted earnings / (loss) per share	(3.17)	(3.68)	(2.58)	(1.39)	(0.85)
Number of shares used for calculation (basic and diluted)	41,085,237	33,626,305	26,564,414	23,766,783	11,406,929

The total number of ordinary shares outstanding as of December 31, 2018, 2017, 2016, 2015 and 2014 was 42,135,448, 36,984,292, 32,421,121, 25,128,242 and 16,935,780, respectively. The registered share capital as of December 31, 2018, 2017, 2016, 2015 and 2014 was DKK 42,135,448, DKK 36,984,292, DKK 32,421,121, DKK 25,128,242 and DKK 4,233,945, respectively.

Selected Consolidated Statement of Financial Position Data:

The following table sets forth selected consolidated statement of financial position data as of the dates indicated:

(EUR'000)	As of December 31, 2018	2017	2016	2015	2014
Cash and cash equivalents	277,862	195,351	180,329	119,649	50,167
Total assets	318,968	210,979	190,071	131,774	58,671
Total liabilities	38,918	23,768	13,458	11,445	12,861
Retained earnings/(accumulated deficit)	(393,307)	(263,210)	(139,313)	(70,808)	(37,886)
Total equity	280,050	187,211	176,613	120,329	45,810

Selected Consolidated Cash Flow Statement Data:

The following table sets forth selected consolidated cash flow statement data for the periods indicated:

	Year Ended December 31,				
(EUR'000)	**2018**	**2017**	**2016**	**2015**	**2014**
Cash flows from / (used in) operating activities	(138,802)	(95,099)	(60,179)	(43,466)	(18,403)
Cash flows used in investing activities	(2,648)	(941)	(672)	(1,039)	(405)
Cash flows from / (used in) financing activities	203,267	124,721	117,462	105,742	47,907

Exchange Rate Information

Our business is primarily conducted in the European Union, and we maintain our books and records in euros. We have presented results of operations in euros. In this annual report, financial figures included in or extracted from our consolidated financial statements have been translated in accordance with the guidelines under IFRS. For convenience of the reader, this annual report also includes other translations from euros to U.S. dollars and U.S. dollars to euros. Unless specified as of a specific date, or otherwise indicated, translations from euros to U.S. dollars and from U.S. dollars to euros were made at a rate of €0.873 to $1.00, the official exchange rate quoted by the European Central Bank at the close of business on December 31, 2018. Such U.S. dollar amounts are not necessarily indicative of the actual amounts of U.S. dollars which could have been actually purchased on exchange of euros on the dates indicated.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business faces significant risks. You should carefully consider all of the information set forth in this annual report and in our other filings with the United States Securities and Exchange Commission ("SEC"), including the following risk factors which we face and which are faced by our industry. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. This report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this report and our other SEC filings. See "Special Note Regarding Forward-Looking Statements" above.

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

We have a limited operating history, no products approved for commercial sale and we may incur significant losses in the future, which makes it difficult to assess our future viability.

We are applying our innovative TransCon™ technologies to build a leading, fully integrated biopharmaceutical company and to develop a pipeline of product candidates with potential best-in-class profiles to address unmet medical needs. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused substantially all of our efforts on our research and development activities and, in particular, developing our lead product candidates, TransCon Growth Hormone, or TransCon hGH, TransCon Parathyroid Hormone, or TransCon PTH, TransCon C-Type Natriuretic Peptide, or TransCon CNP, and our proprietary TransCon technologies. We have only a limited operating history upon which our shareholders and ADS holders can evaluate our business and prospects. Our revenue has been

primarily generated through collaboration agreements under which we have received up-front technology licensing fees, payments for the sale of certain intellectual property rights and payments we receive for services rendered to our collaboration partners and other biopharmaceutical companies. Revenue generated from existing or new collaborations may fluctuate significantly over time. Accordingly, going forward, we may incur significant losses from our operations. We had a net loss of €130.1 million during the year ended December 31, 2018 and a net loss of €123.9 million during the year ended December 31, 2017. Our total equity was €280.1 million as of December 31, 2018 compared to €187.2 million as of December 31, 2017. Neither the net loss nor net profit we have experienced in prior years are necessarily indicative of our future results.

None of our product candidates have been approved for commercial sale by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or similar non-U.S. regulatory authorities, and we have not generated revenues from the sale of approved products. We expect that our annual operating expenses may increase over the next several years as we expand our research and development efforts and prepare for commercialization. Even if we receive milestone payments from our current or future collaboration partners, we may incur substantial operating losses for the foreseeable future as we execute our operating plan. Additionally, we cannot be certain that we will receive any potential milestones under our agreements with our collaboration partners. For a discussion of the risks associated with our preclinical and clinical development programs with, and potential for milestone and other payments from, our collaboration partners, see "—Risks Related to Our Business."

Even if we receive milestone payments or royalty payments from our current or future collaboration partners, we may not be able to achieve or sustain profitability. For example, our receipt of milestone payments or up-front payments from our current and potential collaboration partners may not result in the recognition of revenue in the period received, as we may be required to defer the revenue recognition of such payments over time, and depending upon such requirements and the period of recognition, we may still incur losses even after the receipt of such payments. Therefore, we expect that we may incur significant losses in the future. Possible future losses would have an adverse effect on our shareholders' equity. Further, the net losses or net income we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a reliable indication of our future performance.

We have never generated any revenue from product sales.

We have no products approved for sale and have never generated any revenue from product sales. Our ability to generate revenue from product sales depends on our ability and the ability of our current and future collaboration partners to successfully complete the research and development of our product candidates and obtain the regulatory and marketing approvals necessary to commercialize one or more of our product candidates. We do not anticipate generating revenue from product sales or our royalty rights in the near term. Our ability to generate future revenue from product sales or pursuant to milestone payments or royalties from current and future collaboration partners depends heavily on many factors, including but not limited to:

- completing research and preclinical and clinical development of our product candidates;
- on our own, or together with our strategic collaboration partners, obtaining regulatory approvals for our product candidates;
- negotiating favorable terms of and entering into collaboration, licensing or other arrangements;
- the ability of our collaboration partners to successfully commercialize and/or our ability to commercialize or co-promote our product candidates;
- developing a sustainable and scalable manufacturing process for any of our approved product candidates and establishing and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate, in amount and quality, products to support clinical development and the market demand for our product candidates, if approved;

- obtaining market acceptance of our product candidates, if approved, as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring, in-licensing and/or developing new product candidates;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how, and our ability to develop, manufacture and commercialize our product candidates and products without infringing intellectual property rights of others; and
- attracting, hiring, and retaining qualified personnel.

In cases where we, or our current or future collaboration partners, are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which regulatory approval is granted, the accepted price for the product, the availability of competing products, the ability to get reimbursement for our products at any price and the extent of our royalty rights for that territory. If the number of patients suitable for our product candidates is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the reasonably accepted population for treatment is narrowed by competition, physician choice, treatment guidelines or third-party payor restrictions, we may not generate significant revenue from the sale of such products, even if approved. Our failure to generate revenue from product sales or pursuant to up-front or milestone payments and royalties from current and future collaboration partners would likely depress our market value and could impair our ability to raise capital, expand our business, discover or develop other product candidates or continue our operations.

We may require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, scale back or cease our product development or any other or all operations.

Since our inception, most of our resources have been dedicated to our research and development activities and, in particular, developing our proprietary TransCon technologies and our most advanced product candidates. We have funded our operations primarily through issuance of our preference shares, ordinary shares and convertible debt securities and payments to us under our collaboration agreements. For example, in March 2019, we received $539.8 million (€476.9 million in net proceeds from a public offering of American Depositary Shares (representing our ordinary shares) after deducting the underwriting commissions and estimated offering expenses. As of December 31, 2018, we had cash and cash equivalents of €277.9 million. We believe that we will continue to expend substantial resources for the foreseeable future, including costs associated with research and development, conducting preclinical studies, clinical trials, obtaining regulatory approvals and, eventually, sales and marketing if any of our product candidates is approved. Because the outcome of any clinical trial and/or regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts of additional financing necessary to successfully complete the development, regulatory approval process and commercialization or co-promotion of any of our product candidates.

Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2018 will be sufficient to meet our projected cash requirements for at least the 12 months from the date of this annual report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including, but not limited to:

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;

- the achievement of development, regulatory and commercial milestones resulting in the payment to us from our collaboration partners of contractual milestone payments and the timing of receipt of such payments, if any;
- our ability to collect payments which are due to us from our collaboration partners, which in turn is impacted by the financial standing of our collaboration partners;
- the progress, timing, scope, results and costs of our preclinical studies and clinical trials and manufacturing activities for our product candidates that have not been licensed, including the ability to enroll patients in a timely manner for clinical trials;
- the time and cost necessary to obtain regulatory approvals for our product candidates that have not been licensed and the costs of post-marketing studies that could be required by regulatory authorities;
- the manufacturing, selling and marketing costs associated with product candidates, including the cost and timing of building our sales and marketing capabilities;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the sales price and the availability of adequate third-party coverage and reimbursement for our product candidates;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the number and scope of preclinical and discovery programs that we decide to pursue or initiate;
- the potential acquisition and in-licensing of other technologies, products or assets;
- the time and cost necessary to respond to technological and market developments, including further development of our TransCon technologies;
- our progress (and the progress of our collaboration partners, if any) in the successful commercialization and co-promotion of our most advanced product candidates and our efforts to develop and commercialize our other existing product candidates; and
- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation, including costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of our product candidates.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, scale back or cease our research and development activities, preclinical studies and clinical trials for our product candidates for which we retain such responsibility and our establishment and maintenance of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

Raising additional capital may cause dilution to our holders of shares or ADSs, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, the ownership interest of our shareholders and ADS holders would be diluted, and the terms

may include liquidation or other preferences that adversely affect the rights of our shareholders and ADS holders. Such financing may result in dilution to holders of shares or ADSs, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic partnerships with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Risks Related to Our Business

We are substantially dependent on the success of our product candidates, which may not be successful in nonclinical studies or clinical trials, receive regulatory approval or be successfully commercialized.

To date, we have invested a significant amount of our efforts and financial resources in the research and development of our current product candidates utilizing our proprietary TransCon technologies. In particular, we completed a pivotal phase 3 trial for TransCon hGH in pediatric growth hormone deficiency, or GHD, patients in March 2019, and in 2017, we initiated a long-term extension trial of TransCon hGH and a switch trial of TransCon hGH for those already taking daily growth hormone therapy, for which we completed enrollment in September 2018. We completed a combined phase 1 single and multiple ascending dose study of TransCon PTH for hypoparathyroidism in healthy subjects in May 2018 and we initiated the phase 2 trial of TransCon PTH in patients with hypoparathyroidism in the first quarter of 2019 to evaluate different dosing regimens. We reported preliminary results from a phase 1 clinical trial in healthy subjects of TransCon CNP in November 2018 and we plan to initiate a phase 2 trial of TransCon CNP in pediatric subjects with achondroplasia in the third quarter of 2019. Our near-term prospects, including our ability to finance our operations through the receipt of milestone payments and potential up-front licensing payments and generate revenue from product sales, will depend heavily on our successful development and commercialization of our product candidates, if approved. The clinical and commercial success of our product candidates and our TransCon technologies will depend on a number of factors, including the following:

- the outcome and successful execution of our ongoing and planned clinical trials of TransCon PTH and TransCon CNP;
- our ability and that of our collaboration partners to establish commercial-scale manufacturing processes for our product candidates and devices, which has not yet been demonstrated;
- whether our product candidates' safety, tolerability and efficacy profiles will be satisfactory to the EMA, the FDA and similar regulatory authorities to warrant marketing approval;
- whether the EMA, the FDA or similar regulatory authorities require additional clinical trials prior to approval to market our product candidates;
- the prevalence and severity of adverse side effects of our product candidates;
- the occurrence of adverse events that implicate the TransCon technologies, including among any out-licensed product candidates;
- the timely receipt of necessary marketing authorizations for our product candidates and devices from the EMA, the FDA and similar regulatory authorities;
- our ability and that of our collaboration partners to successfully commercialize our product candidates, if approved for marketing and sale by the EMA, the FDA or similar regulatory authorities, including educating physicians and patients about the benefits, administration and use of such products;
- achieving and maintaining compliance with all applicable regulatory requirements;

- acceptance of our product candidates as safe and effective by patients and the medical community;
- acceptance of our devices, including the TransCon hGH auto-injector and the TransCon PTH drug delivery device and associated Bluetooth connectivity features, by patients and the medical community;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- obtaining and sustaining an adequate level of coverage and reimbursement for our product candidates by third-party payors;
- the effectiveness of our collaboration partners' marketing, sales and distribution strategies and operations;
- our ability and that of our collaboration partners, or any third-party manufacturer we or our collaborators contract with, to manufacture supplies of our product candidates and to develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practice, or cGMP, requirements;
- enforcing intellectual property rights in and to our product candidates;
- avoiding third-party interference, opposition, derivation or similar proceedings with respect to our patent rights, and avoiding other challenges to our patent rights and patent infringement claims; and
- continued acceptable safety profiles of our product candidates following approval, if approved.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of our collaboration partners.

Additionally, as part of our clinical and regulatory approval plan for TransCon hGH for pediatric GHD we conducted a phase 3 trial in a pediatric population with a primary endpoint of annualized height velocity measured at 12 months, for which we released top-line results in March 2019, the heiGHt Trial, and a separate safety study, the fliGHt (switch) Trial, which was designed to evaluate TransCon hGH in subjects who are primarily treatment experienced with daily GH, although a subgroup of younger subjects may be treatment-naïve. In September 2018, we completed enrollment in the fliGHt Trial. Subjects completing either the heiGHt or fliGHt Trials may also enroll in an open-label extension study, the enliGHten Trial, which is designed to provide long-term safety data in approximately 300 patients to support the potential future regulatory filings for TransCon hGH. Accordingly, we cannot be certain that our product candidates will ever be approved or successfully commercialized, or that we will ever generate revenue from sales of such product candidates. If we and our collaboration partners are not successful in completing the development of, obtaining approval for, and commercializing our product candidates, or are significantly delayed in doing so, our business will be harmed.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays in our clinical studies. Furthermore, results of earlier studies and trials may not be predictive of results of future trials.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we, or our current or future collaboration partners, must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process; the results of preclinical and clinical studies of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We may experience delays or setbacks in our ongoing clinical trials, and we do not know whether future clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence a trial, if applicable;
- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain Ethics Committee, institutional review board, or IRB, approval at each site;
- import drug product for use in a trial;
- recruit suitable patients to participate in a trial;
- have patients complete a trial or return for post-treatment follow-up;
- ensure that clinical sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- initiate or add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of product candidate for use in clinical trials.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, our collaboration partner for a product candidate, by the Ethics Committee or IRBs of the institutions in which such trials are being conducted, by an independent data safety monitoring board, or DSMB, for such trial or by European Economic Area, or EEA, Competent Authorities, the FDA or similar regulatory authorities. Such authorities, or we, may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by EEA Competent Authorities, the FDA or similar regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, we are conducting phase 3 pediatric studies of TransCon hGH across clinical sites located in North America, Europe, the Middle East, and Oceania (Australia/New Zealand). Conducting clinical trials in foreign countries presents additional risks that may delay completion of clinical trials. These risks include the failure of physicians or enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. In addition, the EMA or the FDA may determine that the clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product candidate when administered in EEA or U.S. patients, and are thus not supportive of an application for a marketing authorization in the EEA or of a New Drug Application, or NDA, or Biologics License Application, or BLA, approval in the United States. As a result, the EMA or the FDA may not accept data from clinical trials conducted outside the EEA or the United States, respectively, and may require that we conduct additional clinical trials or obtain additional data before we can submit an NDA or BLA in the United States or a marketing authorization application in the EEA. The EMA or the FDA may even require conducting additional clinical trials in the EEA or the United States, respectively.

If there are delays in the completion of, or termination of, any clinical trial of our product candidates or if we are required to conduct additional clinical trials in addition to those we have currently planned, the commercial prospects of our product candidates may be harmed, and our ability to generate revenue from product sales from any of these product candidates will be delayed. In addition, any delays in completing the clinical trials will increase costs, slow down our product candidate development and approval process and jeopardize the ability to commence product sales and generate revenue from product sales. Any of these occurrences may significantly harm our business, financial condition and prospects. Clinical trial delays may also allow our competitors to bring products to market before we do, which could impair our ability to obtain orphan exclusivity for our products that potentially qualify for orphan drug designation. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We depend on collaboration partners to develop and conduct clinical studies with, obtain regulatory approvals for, market and sell our collaboration product candidates, and if such collaboration partners fail to perform as expected, or are unable to obtain the required regulatory approvals for such product candidates, the potential for us to generate future revenue from such product candidates would be significantly reduced and our business would be significantly harmed.

We rely on our collaboration partners to conduct clinical studies of our collaboration product candidates. We have existing collaborations with Sanofi and Genentech. Under these collaborations, we granted Sanofi and Genentech worldwide licenses to develop certain collaboration product candidates in the fields of diabetes (TransCon peptides) and ophthalmology (TransCon anti-VEGF), respectively. Additionally, in connection with the formation of VISEN Pharmaceuticals, or Visen, we granted Visen exclusive rights to develop and commercialize our rare disease endocrinology products based on our proprietary TransCon technologies, including TransCon hGH, TransCon PTH and TransCon CNP, in the People's Republic of China, including Hong Kong, Macau, and Taiwan, or Greater China, for use in all human indications, subject to certain exceptions. We may also enter into collaboration agreements with other parties in the future relating to our other product candidates. Under our existing collaboration agreements, our collaboration partners are responsible for completing all preclinical and clinical development and obtaining and maintaining regulatory approval for the applicable product candidates from the EMA, the FDA, the National Medical Product Administrations of the People's Republic of China, or NMPA, and similar regulatory authorities. Ultimately, if such product candidates are advanced through clinical trials and receive marketing approval from the EMA, the FDA, the NMPA or similar regulatory authorities, such partners will be responsible for commercialization of these collaboration products. The potential for us to obtain future development milestone payments and, ultimately, generate revenue from royalties on sales of such collaboration products depends entirely on successful development, regulatory approval, marketing and commercialization by our collaboration partners.

If our collaboration partners do not perform in the manner we expect or fulfill their responsibilities in a timely manner, or at all, if our agreements with them terminate or if the quality or accuracy of the clinical data they obtain is compromised, the clinical development, regulatory approval and commercialization efforts related to our collaboration product candidates could be delayed or terminated and it could become necessary for us to assume the responsibility at our own expense for the clinical development of such product candidates. In that event, we would likely be required to limit the size and scope of efforts for the development and commercialization of such product candidate, to seek additional financing to fund further development, or to identify alternative collaboration partners, and our potential to generate future revenue from royalties and milestone payments from such product candidate would be significantly reduced or delayed and our business would be harmed. For example, in September 2012, we entered into a collaboration agreement with United Therapeutics for the development and commercialization of TransCon treprostinil and United Therapeutics filed an IND for TransCon treprostinil that was accepted by the FDA in June 2014. In October 2014, we and United Therapeutics terminated the collaboration agreement, and United Therapeutics has transferred the IND for TransCon treprostinil to us. The IND for TransCon treprostinil has since been withdrawn.

Our existing collaborations and any future collaboration arrangements that we may enter into with third parties may not be scientifically or commercially successful. In addition to the risks inherent in the development of a drug product candidate, factors that may affect the success of our collaborations include the following:

- our collaboration partners have the unilateral ability to choose not to develop a collaboration product for one or more indications for which such product has been or is currently being evaluated, and our collaboration partners may choose to pursue an indication that is not in our strategic best interest or to forego an indication that they believe does not provide significant market potential even if clinical data is supportive of further development for such indication;
- our collaboration partners may choose not to develop and commercialize our collaboration products in certain relevant markets;
- our collaboration partners may take considerably more time advancing our product candidates through the clinical and regulatory process than we currently anticipate, which could materially delay the achievement of milestones and, consequently the receipt of milestone payments from our collaboration partners;
- our collaboration partners have substantial discretion under their respective agreements regarding how they structure their efforts and allocate resources to fulfill their obligations to diligently develop, obtain regulatory approval for and commercialize our collaboration products;
- our collaboration partners control all aspects of commercialization efforts under their respective license agreements and may change the focus of their development and commercialization efforts or pursue higher-priority programs and, accordingly, reduce the efforts and resources allocated to their collaborations with us;
- our collaboration partners are solely responsible for obtaining and maintaining all regulatory approvals and we or our collaboration partners may fail to develop a commercially viable formulation or manufacturing process for our product candidates, and we or our collaboration partners may fail to manufacture or supply sufficient drug substance for commercial use, if approved, which could result in lost revenue under such collaborations;
- our collaboration partners may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- if any of our agreements with our collaboration partners terminate, we will no longer have any rights to receive potential revenue under such agreement, in which case we would need to identify alternative means to continue the development, manufacture and commercialization of the affected product candidates, alone or with others;

- our collaboration partners have the discretion to sublicense their rights with respect to our collaboration technology in connection with collaboration product candidates to one or more third parties without our consent;
- our collaboration partners may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive with products on which they are collaborating with us or which could affect our collaboration partners' commitment to the collaboration; and
- if our collaboration partners receive approval for any of the collaboration product candidates, reductions in marketing or sales efforts or a discontinuation of marketing or sales of our product candidates by our collaboration partners would reduce any royalties we could be entitled to receive, which are based on the sales of our product candidates by our collaboration partners.

In addition, the collaboration agreements provide our collaboration partners with rights to terminate such agreements and licenses under various conditions, which if exercised would adversely affect our product development efforts, make it difficult for us to attract new partners and adversely affect our reputation in the business and financial communities. Our collaboration partners have the right to terminate their respective collaboration agreements with us, upon advance written notice, in the event of our uncured material breach of the agreement and for convenience. In addition, Sanofi may terminate its agreement with us in the event we initiate non-infringement, invalidity or unenforceability proceedings with respect to Sanofi patents. Genentech and Visen may also terminate in the event of our bankruptcy or insolvency, and Genentech may additionally terminate if we undergo a change of control in favor of a competitor of Genentech and that competitor does not segregate our company's personnel and activities under the agreement.

In addition, certain provisions in our exclusive license agreement with Genentech may discourage certain takeover or acquisition attempts, including, as noted above, that in the event we undergo a change of control in favor of a competitor of Genentech and that competitor does not segregate our company's personnel and activities under the license agreement, Genentech may terminate the license agreement.

The timing and amount of any milestone and royalty payments we may receive under our agreements with our collaboration partners will depend on, among other things, the efforts, allocation of resources, and successful development and commercialization of our product candidates by our collaboration partners. We cannot be certain that any of the development and regulatory milestones will be achieved or that we will receive any future milestone payments under these agreements. In addition, in certain circumstances we may believe that we have achieved a particular milestone and the applicable collaboration partner may disagree with our belief. In that case, receipt of that milestone payment may be delayed or may never be received, which may require us to adjust our operating plans.

We may form additional strategic collaborations in the future with respect to our proprietary programs, but we may not realize the benefits of such collaborations.

We may form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to our independent programs that we believe will complement or augment our existing business. We have historically engaged, and intend to continue to engage, in partnering discussions with a range of biopharmaceutical companies and could enter into new collaborations at any time. For example, in November 2018, we announced the formation of Visen, a company established to develop, manufacture, and commercialize our endocrinology rare disease therapies in Greater China. In connection with the formation of Visen, we granted Visen exclusive rights to develop and commercialize our rare disease endocrinology products based on our proprietary TransCon technologies, including TransCon hGH, TransCon PTH and TransCon CNP, in Greater China for use in all human indications, subject to certain exceptions. We face significant competition in seeking appropriate strategic partners, and the negotiation process to secure appropriate terms is time-consuming and complex. Any delays in identifying suitable development partners and entering into agreements to develop our product candidates could also delay the commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. Moreover, we may

not be successful in our efforts to establish such a strategic partnership for any future product candidates and programs on terms that are acceptable to us, or at all. This may be for a number of reasons. For example, under our collaboration with Visen, Visen has a right of first negotiation to develop certain of our endocrinology products in Greater China, so our ability to negotiate such a collaboration with suitable third parties may be hampered by such rights we granted to Visen. Additionally, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, and/or third parties may not view our product candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile. Even if we are successful in entering into a strategic alliance or license arrangement, there is no guarantee that the collaboration will be successful, or that any future collaboration partner will commit sufficient resources to the development, regulatory approval, and commercialization of our product candidates, or that such alliances will result in us achieving revenues that justify such transactions.

Our product candidates, other than TransCon hGH, TransCon PTH and TransCon CNP, are in various stages of preclinical development and we may not be successful in our efforts to successfully develop these products or expand our pipeline of product candidates.

A key element of our strategy is to expand our pipeline of product candidates utilizing our proprietary TransCon technologies, and to advance such product candidates through clinical development, either on our own or in conjunction with strategic collaboration partners. Our other product candidates, are in preclinical development and may require significant time and additional research and development before we can file IND or equivalent with regulatory authorities to begin clinical studies. Of the large number of drugs in development, only a small percentage of such drugs successfully complete the EMA or FDA regulatory approval process and are commercialized. Accordingly, even if we are able to continue to fund such development programs, our product candidates may not be advanced to clinical studies or be successfully developed or commercialized. In addition, our preclinical product candidates may not demonstrate the advantages we expect from application of our TransCon technologies in preclinical studies. In such event, we may decide not to progress any such product candidates into clinical trials.

Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Although our research and development efforts to date have resulted in several development programs, we may not be able to develop product candidates that are safe and effective. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- the research methodology used and our TransCon technologies may not be successful in creating potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' intellectual property rights or other types of exclusivity and we may not be able to obtain a license from such third party or the license terms may not be acceptable to us;
- the market for a product candidate may change during our program or we may discover that such market was smaller than initially expected so that such a product may become financially unfeasible to continue to develop;
- a product candidate may be demonstrated to have harmful side effects or not to be effective, or otherwise not to meet other requirements for regulatory approval;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and

- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, or reimbursable by third-party payors, if applicable.

Even if we are successful in continuing to expand our pipeline, through our own research and development efforts or by pursuing in-licensing or acquisition of product candidates, the potential product candidates that we identify or acquire may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize a product pipeline, we may not be able to generate revenue from product sales in future periods or achieve or sustain profitability.

Interim and/or preliminary data from our clinical trials that we have announced, or that we may announce or publish from time to time, may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim or preliminary data from our clinical studies. For example, in November 2018, we announced preliminary data from the phase 1, double-blind, randomized, placebo-controlled trial of TransCon CNP. Interim data for the trials we may complete are subject to the risk that one or more of clinical outcomes may materially change as patient enrollment continues and/or more patient data become available. Preliminary data would also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, any interim and preliminary data should be viewed with caution until the final data are available. Material adverse changes in the final data could significantly harm our business prospects.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we have focused on research programs and product candidates that utilize our proprietary TransCon technologies. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We rely on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for, or commercialize, our product candidates.

We do not currently have the ability to independently conduct clinical trials or nonclinical studies. We rely on medical institutions, clinical investigators, contract laboratories, collaboration partners and other third parties, such as CROs, to conduct clinical trials of our product candidates. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we control only certain aspects of their activities and have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our nonclinical studies and our clinical trials, we remain responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good laboratory practices, or GLPs, for nonclinical studies, and good clinical practices, or GCPs, for clinical studies. GLPs and GCPs are regulations and guidelines enforced by the Competent Authorities of the Member States of the European Economic Area, or

EEA, the FDA and comparable foreign regulatory authorities for all of our products in nonclinical and clinical development, respectively. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third party contractors fail to comply with applicable regulatory requirements, including GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the EMA, the FDA, or similar regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be certain that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations. The failure of our contract manufacturers to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Even if our product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success, which will depend, in part, upon the degree of acceptance among physicians, patients, patient advocacy groups, third-party payors and the medical community.

Even if our product candidates obtain EMA, FDA or other regulatory approvals, and are ultimately commercialized, our product candidates may not achieve market acceptance among physicians, patients, third-party payors, patient advocacy groups and the medical community. The degree of market acceptance, if any, for our most advanced product candidates for which marketing approval is obtained will depend on a number of factors, including:

- the efficacy of the products as demonstrated in clinical trials;
- the prevalence and severity of any side effects and overall safety profile of the product;
- the perceived safety of the TransCon technologies;
- the convenience and features of the auto-injector or drug delivery device used to administer the drug;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment and their willingness to pay for them;
- relative convenience and ease of administration of our products;
- the potential and perceived advantages of our product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the availability of supply of our products and their ability to meet market demand;
- marketing and distribution support for our product candidates;
- the quality of our relationships with patient advocacy groups; and
- coverage and reimbursement policies of government and other third-party payors.

If our product candidates that obtain regulatory approval do not achieve significant market acceptance or commercial success, this could harm our business, results of operations and prospects, and the value of our shares or ADSs.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if any. If any of our product candidates receives marketing approval and subsequently causes undesirable side effects, the ability to market the product candidates could be compromised.

Undesirable side effects caused by TransCon hGH, TransCon PTH, TransCon CNP, or our other product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the EMA, the FDA or similar authorities. In the event that trials conducted by us or our collaboration partners, or trials we conduct with our unlicensed product candidates, reveal a high and unacceptable severity and prevalence of side effects, such trials could be suspended or terminated and the EMA, the FDA or similar regulatory authorities could order our collaboration partners or us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if we successfully develop a product candidate and it receives marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry.

In addition, in the event that any of our product candidates receives regulatory approval and we or others later identify undesirable side effects caused by one of our products, a number of potentially significant negative consequences could occur, including:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or our collaboration partners, may be required to recall the product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof, including the imposition of a REMS or requirements for similar actions, such as patient education, certification of health care professionals or specific monitoring;
- we, or our collaboration partners, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us, or our collaboration partners, from achieving or maintaining market acceptance of a particular product candidate, if approved, and could result in the loss of significant revenue to us, which would harm our results of operations and business.

Competition in the biotechnology and pharmaceutical industries is intense and our competitors may discover, develop or commercialize products faster or more successfully than us. If we are unable to compete effectively our business, results of operations and prospects will suffer.

The markets in which we intend to compete are undergoing, and are expected to continue to undergo, rapid and significant technological changes. Some of our product candidates are for fields in which competitive products already exist and are established. We expect competition to intensify as technological advances are made or new drugs and biotechnology products are introduced. New developments by competitors may render our current or future product candidates and/or technologies non-competitive, obsolete or not economical. Our competitors' products may be more efficacious or marketed and sold more effectively than any of our product candidates.

We are aware of several pharmaceutical and biopharmaceutical companies that have commenced clinical studies of products or have successfully commercialized products addressing areas that we are targeting. For example, several companies are developing sustained release or long-acting products for the treatment of growth hormone deficiency, including GeneScience Pharmaceuticals Co., Ltd., Genexine Inc., JCR Pharmaceuticals Co., Ltd., Novo Nordisk A/S, and OPKO Health, Inc. (in collaboration with Pfizer Inc.). Shire plc owns the rights to Natpara, a treatment for hypoparathyroidism. In addition, we are aware of several academic groups and companies working on making longer-acting agonists of the PTH receptor, or PTH1R. Other companies and groups are developing or commercializing therapies for hypoparathyroidism, including Shire, Chugai Pharmaceutical Co., Ltd., Entera Bio, Extend Biosciences, Massachusetts General Hospital, Alizé Pharma and Eli Lilly and Company. Other companies are developing therapies for achondroplasia, including BioMarin, Therachon, QED Therapeutics and BioClin Therapeutics. BioMarin Pharmaceuticals, Inc. is developing vosoritide for the treatment of achondroplasia, Therachon and BioClin Therapeutics, Inc. are developing compounds for achondroplasia. In addition to product-based competition, our TransCon technologies face technology-based competition as we believe other companies are developing or evaluating enhanced drug delivery and sustained release technologies. In particular, we believe Nektar Therapeutics, OPKO Health, Inc., ProLynx LLC and Serina Therapeutics, Inc. are developing technologies that use reversible linkers and that may be competitive with our TransCon technologies.

It is also possible that our competitors will commercialize competing drugs or treatments before we or our collaboration partners can launch any products developed from our product candidates. We also anticipate that we will face increased competition in the future as new companies enter into our target markets.

Furthermore, to the extent we are developing TransCon product candidates that incorporate already approved drugs, we face competition from the pharmaceutical companies which are currently marketing such approved products. These pharmaceutical companies can generally be expected to seek to delay the introduction of competing products through a variety of means including:

- filing new formulation patent applications on drugs whose original patent protection is about to expire;
- filing an increasing number of patent applications that are more complex and costly to challenge;
- filing suits for alleged patent infringement that automatically delay FDA approval;
- developing patented controlled-release or other "next-generation" products, which may compete with TransCon product candidates;
- establishing exclusive contracts with third party payors; or
- changing product claims and product labeling.

Any one of these strategies may increase the costs and risks associated with our efforts to introduce any of our product candidates and may delay or altogether prevent such introduction.

Many of our competitors have:

- significantly greater name recognition, financial, marketing, research, drug development and technical and human resources than we have at every stage of the discovery, development, manufacturing and commercialization process and additional mergers and acquisitions in the biotechnology industries may result in even more resources being concentrated in our competitors;
- more extensive experience in commercializing drugs, conducting preclinical testing, conducting clinical studies, obtaining regulatory approvals, challenging patents and in manufacturing and marketing pharmaceutical products;
- products that have been approved or are in late stages of development; and
- collaboration arrangements in our target markets with leading companies and research institutions.

If we successfully develop and obtain approval for our product candidates, we will face competition based on many different factors, including:

- the safety and effectiveness of our product candidates;
- the timing of and specific circumstances relating to regulatory approvals for these product candidates;
- the availability and cost of manufacturing, marketing and sales capabilities;
- the effectiveness of our marketing and sales capabilities;
- the price of our product candidates;
- the availability and amount of third-party reimbursement for our product candidates; and
- the strength of our patent position.

In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

Our competitors may develop or commercialize products with significant advantages in regard to any of these factors. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our business, results of operations and prospects, and the value of our shares or ADSs.

For additional information regarding the competitive landscape for our product candidates, see “Item 4 B. Information on the Company – Business Overview – TransCon Product Candidates.”

Our proprietary TransCon technologies include a new approach to extending the residence time and duration of action of a variety of drug products and may not result in any products of commercial value.

Our TransCon technologies have been developed to improve the delivery of a variety of drug products. However, we cannot be certain that our TransCon technologies will be deemed safe or efficacious, nor that any aspects of our TransCon technologies will yield additional product candidates that could enter clinical development and, ultimately, be commercially valuable. Further, one of our two carrier systems, the TransCon hydrogel carrier system, has never been used in humans. As a result, our TransCon hydrogel carriers, when dosed in humans, may fail to perform as we expect. Failure of any of our product candidates to be successfully developed and approved may result in our TransCon technologies being viewed as an ineffective approach to developing drug products which would harm our business and prospects.

We apply our TransCon technologies to both approved and unapproved parent drugs to extend the life of such drugs in the body, and to enhance the overall benefit of a given therapy. Even when applied to approved parent drugs, we have generated limited clinical data on our product candidates using our systemic TransCon technologies with respect to safety and efficacy for long-term treatment in humans. The long-term safety and efficacy of our TransCon technologies and the extended life in the body of our product candidates utilizing TransCon technologies compared to currently approved products is unknown, and it is possible that our product candidates may have an increased risk of unforeseen reactions following extended treatment relative to other currently approved products. If extended treatment with product candidates utilizing TransCon in our ongoing or future clinical trials results in any concerns about the safety or efficacy of our TransCon technologies, we may be unable to successfully develop or commercialize our product candidates.

Product candidates created utilizing the TransCon technologies are new chemical entities that employ novel technologies that have not yet been approved by the FDA, EMA or other regulatory authorities. These regulatory authorities have limited experience in evaluating our technologies and product candidates.

Our TransCon technologies allow for the creation of new molecular entities through the transient conjugation of parent drug molecules to our soluble and microparticle TransCon carrier molecules via our TransCon linkers. We and our collaboration partners are developing product candidates based on these novel technologies, and we intend to work closely with our collaboration partners to understand and deliver the requisite demonstration of safety and efficacy that the FDA, the EMA and other regulatory authorities may seek for the approval of product candidates that incorporate the TransCon technologies. It is possible that the regulatory approval process may take significant time and resources and require deliverables from independent third parties not under our control. For some of our product candidates, the regulatory approval path and requirements may not be clear, which could add significant delay and expense. Delays or failure to obtain regulatory approval of any of the products that we or our collaboration partners develop using our novel technologies would adversely affect our business.

We have limited clinical data on product candidates utilizing the TransCon technology platforms to indicate whether they are safe or effective for long-term use in humans.

Our product candidates transiently link a parent drug molecule to select TransCon carriers via our TransCon linkers. Once injected, we believe that our prodrugs predictably release the unmodified parent drug molecule over time, thus preserving the parent drug's original mode of action, and, we believe, the parent drug's original safety and efficacy profile. We believe that our TransCon carriers remain bound to our TransCon linkers and that they are cleared from the body predominantly by renal filtration and biliary transport with fecal excretion. We have limited clinical data on product candidates utilizing the systemic TransCon technologies to indicate whether they are safe or effective for long-term use in humans, including the safety of any degradation products that may result after the TransCon carrier and TransCon linker are cleaved from the parent drug molecule. As an example, our TransCon prodrugs utilize polyethylene glycol, or PEG, and hydrogels incorporating PEG-based polymers as TransCon carriers. Although the safety and efficacy of PEG and permanently PEGylated proteins has been demonstrated within their respective indications by the approval of drugs such as PegIntron®, PegaSys®, Neulasta®, Somavert®, Cimzia®, Krystexxa®, Adynovate® and Rebinyn® and we are not aware of any evidence for PEG-related safety issues with PEGylated proteins in the clinic, health authorities, including the EMA, have historically posed general questions relating to the distribution, elimination, and the potential for PEG accumulation to pharmaceutical companies involved in the development of PEGylated drug products. If treatment with any of our product candidates in our clinical trials results in concerns about their safety or efficacy, we and our collaboration partners may be unable to successfully develop or commercialize any or all of our TransCon technologies based product candidates or enter into collaborations with respect to our product candidates.

We have limited clinical data on TransCon PTH and TransCon CNP and no clinical data on our other preclinical product candidates, to indicate whether they are safe or effective for long-term use in humans.

We have generated limited clinical data on TransCon PTH and TransCon CNP. It is unknown whether long-term repeated administration of TransCon PTH or TransCon CNP could result in issues that may adversely affect safety. If extended treatment with TransCon PTH, TransCon CNP, or any of our other preclinical product candidates, in our clinical trials, results in any safety or efficacy concerns, we may be unable to successfully develop or commercialize our product candidates or enter into collaborations with respect to our product candidates.

We may seek orphan drug designation for some of our product candidates and we may be unsuccessful, or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity, for product candidates for which we obtain orphan drug designation.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs or biologics intended to treat relatively small patient populations as orphan drug products. Under the U.S. Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

If a drug or biologic with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug or biologic is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. If our competitors are able to obtain orphan drug exclusivity prior to us, for products that constitute the “same drug” and treat the same indications as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time. The applicable period is seven years in the United States.

As part of our business strategy, we intend to pursue orphan drug designation for certain of our product candidates. For example, in June 2018 we were granted orphan drug designation by the FDA for TransCon PTH and in February 2019 we were granted orphan drug designation by the FDA for TransCon CNP. However, we may be unsuccessful in obtaining orphan drug designation for other product candidates, and may be unable to maintain the benefits associated with orphan drug designation. Even if we obtain orphan drug exclusivity for any of our product candidates, that exclusivity may not effectively protect those product candidates from competition because different drugs can be approved for the same condition, and orphan drug exclusivity does not prevent the FDA from approving the same or a different drug in another indication. Even after an orphan drug is approved, the FDA can subsequently approve a later application for the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan-drug-exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA

approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty, and any processes adopted by the FDA to implement the BPCIA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our future product candidates approved as a biological product under a BLA should qualify for the twelve-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

We lack direct sales capabilities, and are wholly dependent on collaboration partners for the commercialization of our product candidates. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to commercialize any of our product candidates.

We have no direct sales or distribution capabilities. We have entered into collaboration agreements with third parties to market and sell product candidates in the fields of diabetes (unspecified TransCon Peptides) and ophthalmology (TransCon anti-VEGF). Except for our license agreements with Visen for Greater China, we have no sales, marketing or distribution agreements for TransCon hGH, TransCon PTH, TransCon CNP, or our other product candidates. We may enter into arrangements with third parties to market and sell certain of our other product candidates in one or multiple geographies. We may not be able to enter into such marketing and sales arrangements with others on acceptable terms, if at all. To the extent that we enter into marketing and sales arrangements with other companies, our revenues, if any, will depend on the terms of any such arrangements and the efforts of others. These efforts may turn out not to be sufficient.

We currently do not have our own sales organization. To commercialize any of our product candidates, we or our collaboration partners must build and/or maintain marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we or our collaboration partners may not be successful in doing so. If one or more of our product candidates receives regulatory approval, we may establish a specialty sales organization with technical expertise and supporting distribution capabilities to co-promote and/or commercialize our product candidates, which will be expensive and time consuming. As a company, we have no prior experience in the sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, comply with regulatory requirements applicable to the marketing and sale of drug products and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities with respect to a non-licensed product candidate would adversely impact the commercialization of such product candidate.

We may choose to work with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates.

We rely on third parties to manufacture our preclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product candidate and device.

We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing our products and product candidates for the potential pivotal clinical studies and/or commercial manufacturing of our products and product candidates. We depend on our collaboration partners and other third parties to manufacture and provide analytical services with respect to our most advanced product candidates and device.

In addition, if our product candidates are approved, to produce the quantities necessary to meet anticipated market demand, we and/or our collaboration partners will need to secure sufficient manufacturing capacity with third-party manufacturers. If we and/or our collaboration partners are unable to produce our product candidates in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, our revenues and gross margins could be adversely affected. To be successful, our product candidates must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. We and/or our collaboration partners will regularly need to secure access to facilities to manufacture some of our product candidates commercially. All of this will require additional funds and inspection and approval by the Competent Authorities of the Member States of the EEA, the FDA and other regulatory authorities. If we and/or our collaboration partners are unable to establish and maintain a manufacturing capacity within our planned time and cost parameters, the development and sales of our products and product candidates as well as our business, results of operations and prospects, and the value of our shares or ADSs could be adversely affected.

We and/or our collaboration partners may encounter problems with aspects of manufacturing our collaboration products and product candidates, including the following:

- production yields;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with FDA and EEA regulations;
- production costs; and
- development of advanced manufacturing techniques and process controls.

We evaluate our options for clinical study supplies and commercial production of our product candidates on a regular basis, which may include use of third-party manufacturers, or entering into a manufacturing joint venture relationship with a third party. We are aware of only a limited number of companies on a worldwide basis who operate manufacturing facilities in which our product candidates can be manufactured under cGMP regulations, a requirement for all pharmaceutical products. We cannot be certain that we or our collaboration partners will be able to contract with any of these companies on acceptable terms, if at all, all of which could harm our business, results of operations and prospects, and the value of our shares or ADSs.

In addition, we or our collaboration partners, as well as any third-party manufacturer, will be required to register such manufacturing facilities with the FDA (and have a U.S. agent for the facility, if outside the United States), the Competent Authorities of the Member States of the EEA, and other regulatory authorities. The facilities will be subject to inspections confirming compliance with the FDA, the Competent Authorities of the Member States of the EEAs, or other regulatory authority cGMPs requirements. We do not control the manufacturing process of our product candidates, and, other than with respect to our collaboration product candidates, we are dependent on our contract manufacturing partners for compliance with cGMPs regulations for manufacture of both active drug substances and finished drug products. If we or our collaboration partners or any third-party manufacturer fails to maintain regulatory compliance, our business, financial condition and results of operations may be harmed, and the FDA, the Competent Authorities of the Member States of the EEA, or other regulatory authorities can impose regulatory sanctions that range from a warning letter to withdrawal of approval to seeking product seizures, injunctions and, where appropriate, criminal prosecution.

Under our agreements with Genentech and Sanofi, the manufacturing of our collaboration product candidates is completed by the applicable collaboration partner. We are entirely dependent on Genentech and Sanofi for all aspects of the manufacturing and validation process, as well as providing all commercial supply of our collaboration product candidates. Under our collaboration with Visen, we are obligated to use commercially reasonable efforts to supply relevant product candidates for Visen to conduct clinical trials therefor, and will negotiate in good faith with Visen the terms and conditions governing our commercial supply of relevant

products to Visen. In turn, we currently rely on third party manufacturers in fulfilling our supply obligations to Visen. For additional information regarding the risks of our dependence on our collaboration partners, see the risk factors above "—We are substantially dependent on the success of our product candidates, which may not be successful in nonclinical studies or clinical trials, receive regulatory approval or be successfully commercialized" and "—We depend on collaboration partners to develop and conduct clinical studies with, obtain regulatory approvals for, and market and sell our collaboration product candidates, and if such collaboration partners fail to perform as expected, or are unable to obtain the required regulatory approvals for such product candidates, the potential for us to generate future revenue from such product candidates would be significantly reduced and our business would be significantly harmed."

If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or similar regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, the Competent Authorities of the Member States of the EEA, or a similar regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. Any significant delay or discontinuation in the supply of such materials would delay completion of our clinical studies or clinical studies conducted by our collaboration partners who rely on us for supply, and harm our business.

There are a limited number of suppliers for raw materials that we use to manufacture our drugs, and there may be a need to identify alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical studies, and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Although we generally do not begin a clinical study unless we believe we have on hand, or will be able to manufacture, a sufficient supply of a product candidate to complete such study, and we currently envision that Visen, who relies on us for clinical supply of our product candidates, would do the same, any significant delay or discontinuity in the supply of a product candidate, or the raw material components thereof, for a clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our or Visen's clinical studies, product testing, and potential regulatory approval of our product candidates, which could harm our business and results of operations.

Any inability to obtain suppliers, including an inability to obtain, or delay in obtaining, approval of a supplier from the Competent Authorities of the Member States of the EMA, the FDA or other regulatory authorities, would delay or prevent the clinical development and commercialization of our product candidates, and could impact our ability to meet supply obligations to collaboration partners for the development of, or future marketing and sale, of our product candidates.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

Our business exposes us to potential product liability risks which are inherent in research and development, preclinical and clinical studies, manufacturing, marketing and use of our product candidates. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims may be expensive to defend and may result in judgments against us which are potentially punitive. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize or co-promote our product candidates.

It is generally necessary for us to secure certain levels of insurance as a condition for the conduct of clinical studies. We believe that our product liability insurance for clinical studies is sufficient to cover claims. We currently maintain liability insurance with certain specified coverage limits. We cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop. We currently carry product liability insurance covering use in our clinical trials in the amount of $20 million in the aggregate on our primary insurance policy and $20 million in the aggregate on our excess insurance policy. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various, limits, exclusions and deductibles, and given these various limits, exclusions and deductibles, we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms.

We will need to significantly increase the size of our organization and we may have difficulties in managing our growth and expanding our operations successfully.

As of December 31, 2018, we had 216 full-time employees worldwide, with key facilities in Denmark, Germany, and the United States. As we and/or our collaboration partners advance our product candidates through the development and commercialization process, we will need to expand managerial, operational, financial and other resources to manage our operations, preclinical and clinical trials, research and development activities, regulatory filings, manufacturing and supply activities, and any marketing and commercialization activities or contract with other organizations to provide these capabilities for us. As operations expand, we expect that we will need to manage additional relationships with various collaboration partners, suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures across a global organization. Such growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we either internally, together with our collaboration partners or through third party contractors, as applicable:

- expand our general and administrative functions;
- identify, recruit, retain, incentivize and integrate additional employees;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties;
- establish and build a marketing and commercial organization; and
- continue to improve our operational, legal, financial and management controls, reporting systems and procedures.

If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and regulations regarding corporate governance practices. Our senior management and other personnel need to devote a substantial amount of time to ensure that we maintain compliance with all of these requirements. Moreover, the reporting requirements, rules and regulations increase our legal and financial compliance costs and make some activities more time consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as members of our senior management, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the Securities and Exchange Commission, or SEC, which generally require our senior management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the year ended December 31, 2015, Section 404 required an annual management assessment of the effectiveness of our internal control over financial reporting, and beginning with the year ended December 31, 2018, we are required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting.

As we grow our business and enter into new activities, and as the reporting requirements increase, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, as we did as of December 31, 2015, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated. We may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of the ADSs to fall. In addition, as a public company we are required to file accurate and timely annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of the ADSs from the Nasdaq Global Select Market or other adverse consequences that would harm our business.

Our operating results may vary significantly from period to period and these variations may be difficult to predict.

Our potential future revenues and operating results are expected to vary significantly from period to period due to a number of factors. Many of these factors are outside of our control. These factors include:

- the timing of regulatory approvals, if any, for our most advanced product candidates;
- the initiation of intellectual property litigation by third parties or by us;
- the amount and timing of operating costs and capital expenditures relating to the expansion of our business operations and facilities;
- the timing of the commencement, completion or termination of collaboration agreements;
- the timing and amount of payments to us under our collaboration agreements, if any;
- the introduction of new products and services by us, our collaboration partners or our competitors;
- delays in preclinical testing and clinical studies;
- changes in regulatory requirements for clinical studies;
- costs and expenses associated with preclinical testing and clinical studies; and
- payment of license fees for the right to use third-party proprietary rights.

Our revenues in any particular period may be lower than we anticipate and, if we are unable to reduce spending in that period, our operating results will be harmed.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

We may consider strategic transactions, such as acquisitions of companies, asset purchases, and in-licensing or out-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our senior management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- up-front, milestone and royalty payments, equity investments and financial support of new research and development candidates including increase of personnel, all of which may be substantial;
- exposure to unknown liabilities, including potential indemnification claims from a potential spin-off or out-license of certain of our intellectual property rights;
- disruption of our business and diversion of our management’s time and attention to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;

- higher-than-expected acquisition and integration costs;
- lower-than-expected benefits, from out-licensing or selling our technology, intellectual property or any of our subsidiaries or, from in-licensing intellectual property or purchasing assets;
- write-downs of assets or goodwill or impairment charges;
- difficulty and cost in combining or separating the operations and personnel of any acquired or sold businesses with our existing operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired or sold businesses due to changes in our senior management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although we cannot be certain that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could harm our business, results of operations, financial condition and prospects.

Exchange rate fluctuations or abandonment of the euro currency may harm our results of operations and financial condition.

Due to the international scope of our operations, fluctuations in exchange rates, particularly between the euro, the Danish krone and the U.S. dollar, may adversely affect us. Although we are based in Denmark, we source research and development, manufacturing, consulting and other services from several countries. In addition, our arrangements with our collaboration partners are denominated in euros and U.S. dollars. Further, potential future revenue may be derived from abroad, including from the United States. We currently attempt to limit our exposure to exchange rate risks by maintaining cash positions in the currencies in which we expect to incur the majority of our future expenses; however, for a variety of reasons we may be unable to maintain cash positions in the currencies in which we expect to incur the majority of our future expenses and we may fail to predict the currency of our future expenses, accurately or at all. As a result, our business and the price of the ADSs may be affected by fluctuations in foreign exchange rates between the euro and these other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period. We currently do not enter into foreign exchange contracts to cover our exposure to exchange rate fluctuations, or any other form of exchange rate hedging arrangements. If we fail to manage foreign exchange risk adequately our business, results of operations and prospects, and the value of our shares or ADSs may be adversely affected.

In addition, the possible abandonment of the euro by one or more members of the European Union could harm our business in the future. Despite measures taken by the European Union to provide funding to certain E.U. member states in financial difficulties and by a number of European countries to stabilize their economies and reduce their debt burdens, it is possible that the euro could be abandoned in the future as a currency by countries that have adopted its use. This could lead to the re-introduction of individual currencies in one or more E.U. member states. The effects on our business of a potential dissolution of the European Union, the exit of one or more E.U. member states from the European Union or the abandonment of the euro as a currency, are impossible to predict with certainty, and any such events could harm our business, financial condition and results of operations.

The United Kingdom's pending withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

In June 2016, a majority of voters in the United Kingdom elected to withdraw from the European Union in a national referendum, which is generally referred to as Brexit. In March 2017, the United Kingdom delivered notice under Article 50 of the Lisbon Treaty of its intent to leave the European Union. The United Kingdom is currently scheduled to leave the European Union on April 12, 2019, unless this date is extended. To date there

has been no agreement between the European Union and the United Kingdom on the terms of the exit. Brexit, the subsequent high-profile failures of the United Kingdom to agree on an exit strategy, and the pending withdrawal of the United Kingdom, may lead to legal uncertainty and potentially divergent laws and regulations between the United Kingdom and the European Union, as the United Kingdom determines which EU laws to replicate or replace and this uncertainty may persist for years. As a result of Brexit, other European countries may seek to conduct referenda with respect to their continuing membership with the European Union. Given these possibilities and others we may not anticipate, as well as the absence of comparable precedent, it is unclear what financial, regulatory and legal implications the withdrawal of the United Kingdom from the European Union would have and how such withdrawal would affect us, and the full extent to which our business could be adversely affected.

These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of the ADSs.

Risks associated with our international operations, including seeking and obtaining approval to commercialize our product candidates in foreign jurisdictions, could harm our business.

We engage extensively in international operations, which include seeking marketing approval for certain of our product candidates in foreign jurisdictions. We expect that we are or will be subject to additional risks related to entering into these international business markets and relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing U.S. and non-U.S. drug import and export rules;
- reduced protection for intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems, and different competitive drugs;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from development work conducted by these distributors; and

- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

The manufacture of our TransCon product candidates is dependent upon third party manufacturers that are based in other parts of the world, including Europe and Japan. This manufacturing process requires that the components used in our product candidates are transported long distances, through multiple countries, which increases the risk that issues in the global supply chain or other disruptions to the international marketplace could harm our business.

The parent drug, drug substance, drug product and other components of our product candidates are currently acquired from single-source suppliers. The loss of these suppliers, or their failure to supply could materially and adversely affect our business.

Our growth hormone parent drug as well as our TransCon hGH drug substance are supplied by Fujifilm Diosynth Biotechnologies UK Limited, or Fujifilm, pursuant to our agreement with Fujifilm. TransCon hGH drug product in vials is manufactured by Rentschler Fill Solutions GmbH, or Rentschler, pursuant to our agreement with Rentschler. TransCon hGH drug product in dual chamber cartridges will be supplied by Vetter Pharma Fertigung for use in our drug delivery device made by Philips Medisize A/S (formerly Medicom Innovation Partner A/S). The intermediates of our proprietary TransCon linkers are made by CARBOGEN AMCIS AG under an agreement with CARBOGEN AMCIS AG and accompanying purchase orders. For products that utilize soluble TransCon carriers, NOF Corporation (Japan), or NOF, supplies PEGs. Furthermore, NOF is responsible for coupling the TransCon linker used for TransCon hGH to mPEG under manufacturing agreements and accompanying purchase orders. Our PTH as well as our TransCon PTH drug substance is supplied by Bachem, Switzerland, pursuant to our agreement with Bachem. TransCon PTH drug product in vials is manufactured by Baccinex, SA, Switzerland in collaboration with Bachem. We expect Vetter Pharma Fertigung to manufacture TransCon PTH drug product in cartridges and assemble the cartridges with a drug delivery device made by Ypsomed AG. Intermediate for TransCon CNP is supplied by Corden Pharma, Switzerland and CNP drug substance is supplied by Wacker Biotech, Germany. Our TransCon CNP drug product in vials is manufactured by Rentschler pursuant to our agreement with Rentschler. We do not currently have any other suppliers for the drug substance, drug product or other components of our product candidates for TransCon hGH, TransCon PTH and TransCon CNP, although we believe that there are alternate sources of supply that could satisfy our clinical and commercial requirements, we cannot provide assurance that identifying alternate sources and establishing relationships with such sources would not result in significant delays in the development of our product candidates. Additionally, we may not be able to enter into supply arrangements with alternative suppliers on commercially reasonable terms or at all. A delay in the development of our product candidates or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers could have a material adverse impact upon on our business.

We may not be successful in our efforts to identify additional product candidates based on our TransCon technologies.

An important element of our strategy is to develop new products and product candidates based on our TransCon technologies. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including that:

- the research methodology used may not be successful in identifying potential product candidates; or
- potential product candidates may, on further study, be shown to have inadequate efficacy, harmful side effects or other characteristics suggesting that they are unlikely to be effective or safe products, or that they may not be sufficiently differentiated or offer substantial improvement over the currently available treatment options or standard of care in a given therapeutic category.

If we are unable to develop suitable product candidates through internal research programs or otherwise, we will not be able to increase our revenues in future periods, which could harm our business, results of operations and prospects, and the value of our shares or ADSs.

We are highly dependent on the services of our President and Chief Executive Officer, Jan Møller Mikkelsen, and if we are not able to retain this member of our senior management or recruit additional management, clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified personnel. We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

In particular, we are highly dependent upon Jan Møller Mikkelsen, our President and Chief Executive Officer. The loss of services of this individual could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates.

We may have difficulties in attracting and retaining key personnel, and if we fail to do so our business may suffer.

We are highly dependent on the principal members of our senior management and scientific staff, the loss of whose services could adversely affect the achievement of planned development objectives. Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. This is particularly true in Heidelberg, Germany where we operate our research and development activities. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

For us to further expand our product development plans, we will need to hire additional qualified scientific personnel to perform research and development. We will also need to hire personnel with expertise in clinical testing, government regulation, sales and marketing, and finance, and might need to hire personnel with expertise in manufacturing. We may not be able to attract and retain personnel on acceptable terms, given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. Although we may be successful in attracting and retaining suitably qualified scientific personnel, there can be no assurance that we will be able to attract and retain such personnel on acceptable terms given the competition for experienced scientists from numerous pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions. Our failure to do so could adversely affect our business, results of operations and prospects, and the value of our shares or ADSs.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs and other critical business functions.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our regulatory approval efforts, and the loss of research data could result in delays of our research and development efforts and it would be expensive to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Risks Related to Government Regulatory and Legal Requirements

The regulatory approval processes of the EMA, the FDA and comparable authorities are lengthy, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA, E.U. legislative bodies and other regulatory authorities in the United States, the EEA and other jurisdictions, which regulations differ from country to country. Neither we nor any of our collaboration partners is permitted to market any drug product in the United States until we receive marketing approval from the FDA. Equally, neither we nor any of our collaboration partners is permitted to market any drug product in the EEA until we receive a marketing authorization from the EMA or EEA Member State Competent Authorities. We have not submitted an application or obtained marketing approval for any of our product candidates anywhere in the world.

Obtaining regulatory approval of an NDA or BLA, can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S., EEA and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

- warning letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of regulatory approval of products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending NDAs or BLAs, marketing authorization applications, or supplements to approved NDAs or BLAs or extensions or variations to marketing authorizations.

Prior to obtaining approval to commercialize a drug or biologic candidate in the United States, the EEA or other regions, we or our collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the EMA, the FDA or other similar regulatory authorities, that such drug candidates are safe and effective for their intended uses. The number of nonclinical studies and clinical trials that will be required for FDA, or EMA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the EMA, the FDA and other regulatory authorities. Administering drug or biologic candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the EMA, the FDA or other regulatory authorities denying approval of a product candidate for any or all targeted indications.

The time required to obtain approval by the EMA, the FDA and comparable authorities is unpredictable, typically takes many years following the commencement of clinical studies, and depends upon numerous factors. The EMA, the FDA and comparable authorities have substantial discretion in the approval process and we may encounter matters with the EMA, the FDA or such comparable authorities that requires us to expend additional time and resources and delay or prevent the approval of our product candidates. For example, the FDA or EMA may require us to conduct additional studies or trials for drug or biologic products either prior to or post-approval, such as additional drug-drug interaction studies or safety or efficacy studies or trials, or it may object to elements of our clinical development program such as the number of subjects in our current clinical trials from the United States or Europe. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or result in a decision not to approve an application for regulatory approval. Despite the time and expense exerted, failure can occur at any stage. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the EMA, the FDA or other comparable foreign regulatory authorities may disagree with the design or implementation of our, or our collaboration partners', clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which approval is sought;
- the EMA, the FDA or comparable foreign regulatory authorities may disagree with the interpretation of data from preclinical studies or clinical studies;
- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of a NDA or BLA, marketing authorization application, or other submission or to obtain regulatory approval in the United States, the EEA or elsewhere;
- we, or our collaboration partners, may be unable to demonstrate to the EMA, the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the EMA, the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers responsible for clinical and commercial supplies; and
- the approval policies or regulations of the EMA, the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical studies, may result in our failure to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. Additionally, if the EMA, the FDA or comparable foreign regulatory authorities require that we conduct additional clinical studies, place limitations on our label, delay approval to market our product candidates or limit the use of our products, our business and results of operations may be harmed.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, may impose a REMS, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

We do not have and may never obtain the regulatory approvals we need to market our product candidates.

We have not yet received any regulatory approvals required for the commercial sale of TransCon hGH, TransCon PTH, TransCon CNP, or any of our other product candidates in the United States, the EMA or in any other jurisdiction. Furthermore, we have yet to submit an NDA or BLA to the FDA, or a Marketing Authorization Application, or MAA, to the EMA, national regulatory authorities in Europe or to any international regulatory authorities for any of our product candidates. We have only limited experience in filing and pursuing applications necessary to obtain regulatory approval or licensure, and we cannot be certain that any of our product candidates will be approved or licensed for marketing. The process of applying for regulatory approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the product candidates involved. If any or all of our product candidates are not approved, this could harm our business, results of operations and prospects, and the value of our shares or ADSs.

If we are unable to file an MAA for approval to the EMA for our product candidates, or if we are required to generate additional data related to safety and efficacy, to obtain approval from the FDA for any of our product candidates, we may be unable to meet our anticipated development and commercialization timelines.

While we have an active IND with the FDA for TransCon hGH, and we have completed substantive discussions with the FDA regarding the development of TransCon hGH in pediatric growth hormone deficiency, and we believe we are satisfying the necessary criteria, there is no guarantee that FDA requirements will not change between now and the time of our filing in the United States. We have not yet filed an MAA with the EMA for any of our product candidates. Depending on the data that may be required by the EMA for approval, we may be required to conduct substantial new research and development activities beyond those in which we currently plan to engage to obtain approval of our product candidates. Such additional new research and development activities would be costly and time consuming.

We are developing an auto-injector to facilitate the administration of the product by end-users and additional time may be required to obtain regulatory approval for our auto-injector.

We are developing an auto-injector with Phillips Medisize A/S (formerly Medicom Innovation Partner A/S) to facilitate the administration of TransCon hGH by patients. In addition, we are developing a drug delivery device with Ypsomed to facilitate the administration of TransCon PTH by patients. We anticipate the EMA, the FDA and other similar regulatory authorities may require approval of our auto-injector and TransCon PTH drug delivery device as part of the approval of TransCon hGH and TransCon PTH. Because of our auto-injector and TransCon PTH drug delivery device, the FDA's review of TransCon hGH and/or TransCon PTH may include the participation of both the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health, which may complicate or prolong the review, and in the EEA the EMA's review may require the involvement of an EU Notified Body. As a result, we may experience delays for our auto-injector and TransCon hGH and/or our drug delivery device of TransCon PTH and TransCon PTH.

Safety issues with the parent drugs or other components of our product candidates, or with approved products of third parties that are similar to our product candidates, could give rise to delays in the regulatory approval process.

Our product development portfolio consists of prodrugs that are new molecular entities that incorporate existing parent drug molecules, many of which have been previously approved by the EMA, the FDA or other foreign regulatory authorities. Discovery of previously unknown problems with any of the parent drugs that we use in our TransCon product candidates may result in restrictions on its permissible uses, including withdrawal of the product from the market.

Additionally, problems with approved parent drugs marketed by third parties that utilize the same therapeutic target as the parent drug we use in our TransCon product candidates could adversely affect the development of our product candidates.

Any failure or delay in commencing or completing clinical trials or obtaining regulatory approvals for our product candidates would delay commercialization of the product candidates and severely harm our business and financial condition.

We are subject to extensive and costly government regulation. If we fail to obtain or maintain governmental approvals, we will not be able to commercialize our product candidates and our business will suffer.

Pharmaceutical products, including product candidates employing our TransCon technologies, are subject to extensive and rigorous government regulation. The FDA, the EMA and other regulatory authorities regulate the development, testing, manufacture, safety, efficacy, record- keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. If products employing our TransCon technologies are marketed in countries outside of the European Union and the United States, they will also be subject to extensive regulation by other governments. The regulatory review and approval or licensing process, including preclinical testing and clinical studies of each product candidate, is lengthy, expensive and uncertain. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA, EMA and/or EEA Competent Authorities for each indication to establish the candidate's safety and efficacy. The approval process takes many years, requires substantial resources, involves post-marketing surveillance, and may involve ongoing post-marketing studies. While clinical studies are designed with scientific advice from regulatory authorities, such plans must often be put in place years in advance of application for marketing approval. At the time of such application, the clinical and regulatory environment may have changed significantly as a result of new scientific discoveries, competitor product evaluations, changes in medical health care policies, new technical standards and other factors beyond our control.

Regulators can refuse marketing approval, or can require us or our collaboration partners to repeat previous clinical studies or conduct further clinical studies. A pre-approval inspection of manufacturing facilities by regulatory authorities may need to be completed before marketing approval can be obtained, and such facilities will be subject to periodic inspections that could prevent or delay marketing approval, or require the expenditure of financial or other resources to address. If we or our collaboration partners do not succeed in obtaining regulatory approval, or succeed only after delays, this could have a material effect on our ability to generate revenues. Delays in obtaining regulatory approvals may:

- adversely affect the successful commercialization of any product that we or our collaboration partners develop;
- impose costly procedures on us or our collaboration partners;
- diminish any competitive advantages in the market place that we or our collaboration partners may attain; and
- adversely affect our receipt of revenues or royalties.

Material changes to an approved product, such as manufacturing changes or additional labeling claims, require further FDA and EMA and/or EEA Competent Authorities review and approval before marketing. Once obtained, any approvals may be withdrawn or revoked because of unforeseen safety, effectiveness or potency concerns or failure to comply with governmental regulations. Further, if we, our collaboration partners or our contract manufacturers fail to comply with applicable FDA, EMA, and/or EEA Competent Authorities regulatory requirements at any stage during the regulatory process, the FDA, EMA, and/or EEA Competent Authorities and other regulatory authorities may impose sanctions, including:

- delays;
- warning letters;
- fines;

- importation restrictions;
- product recalls or seizures;
- injunctions;
- refusal of the FDA, EMA or other regulatory authorities to review pending market approval applications or supplements to approval applications;
- total or partial suspension of production;
- suspension or debarment from selling FDA-regulated products to the U.S. government for periods of time that vary depending on the cause of such suspension or debarment;
- civil penalties;
- withdrawal or revocation of previously approved marketing applications or licenses; and
- criminal prosecutions.

Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and review, which may result in significant additional expense. Additionally, any product candidates, if approved, could be subject to labeling and other restrictions and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

The governmental regulation of the development of products and product candidates extends beyond clinical studies to approval required for their sale and monitoring of such products after sale. This regulation, approval and monitoring is the responsibility of numerous authorities in Denmark, the United States, the European Union and authorities in other territories. Following any regulatory approval of a product candidate, we, our collaboration partners and the manufacturers of our products will be subject to continuing regulatory obligations, including safety reporting requirements, regulatory oversight of product promotion and marketing, and cGMP requirements. Furthermore, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These regulations cover all aspects of manufacturing, testing, quality control and record keeping of our products. If we or our collaboration partners or manufacturers fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our third party contract manufacturers will be subject to continual review and periodic inspections to assess compliance with regulatory requirements. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. Regulatory authorities may also impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs to assure compliance.

In the United States, advertising and promotional materials must comply with FDA rules in addition to other potentially applicable U.S. laws. In particular, the promotional claims that we would be permitted to make for our products would be limited to those supported by the approved product labeling. In addition, under the Federal Food, Drug, and Cosmetic Act, particular restrictions are placed on the distribution of human growth hormone products, potentially including TransCon hGH. The distribution of product samples to physicians must also comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to International Conference on Harmonisation

of Technical Requirements for Registration of Pharmaceuticals for Human Use and the FDA's cGMP requirements. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. Sales, marketing, and scientific/educational grant programs must comply with the U.S. Anti-Kickback Statute, the False Claims Act, as amended, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to U.S. consumer protection and unfair competition laws.

We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription pharmaceutical products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have FDA approval.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- warning letters, fines or holds on clinical trials;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- injunctions or the imposition of civil or criminal penalties;
- suspension or revocation of existing regulatory approvals;
- suspension of any of our future or ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications submitted by us;
- restrictions on our or our contract manufacturers' operations; or
- product seizure or detention, or refusal to permit the import or export of products.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

In addition, the FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Within the European Union, once a Marketing Authorization is obtained, numerous post-approval requirements also apply, and as in the United States, the off-label promotion of medicinal products is not permitted. The requirements are regulated by both E.U. regulations (such as reporting of adverse events) as well as national applicable regulations (related to prices and promotional material).

The regulatory requirements relating to the manufacturing, testing, marketing and sale of pharmaceutical products are subject to periodic change. This may impact our ability and the ability of our collaboration partners to conduct clinical studies in the European Union. Changes in the regulations governing us could increase costs and adversely affect our business.

Furthermore, companies developing pharmaceutical products are facing increased demands to publish clinical trial results. Any such publication by us may, in addition to the additional cost of the publication, lead to investors misinterpreting the published data due to its technical and scientific nature, which, in turn, may adversely affect our business, results of operations and prospects and the value of our shares or ADSs.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Third-party payor coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford treatments such as ours, assuming approval. Our ability to achieve acceptable levels of coverage and reimbursement for drug treatments by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract additional collaboration partners to invest in the development of our product candidates. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Third-party payors increasingly are challenging prices charged for pharmaceutical products, medical devices and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug is available. It is possible that a third-party payor may consider our product candidate and the generic parent drug as substitutable and only offer to reimburse patients for the generic drug. Even if we show improved efficacy or improved convenience of administration with our product candidate, pricing of the existing parent drug may limit the amount we will be able to charge for our product candidate. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs, biologics and medical devices will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs, biologics and medical devices. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates, if approved, and on related parent drugs. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We and our collaboration partners and contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

We depend on third parties to manufacture products employing our TransCon technologies. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. All entities involved in the preparation of product candidates for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Manufacturing facilities are subject to pre-approval and ongoing periodic inspection by the FDA, EEA Competent Authorities and other corresponding governmental authorities, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing of products employing our TransCon technologies. After regulatory approvals or licensure are obtained, the subsequent discovery of previously unknown manufacturing, quality control or regulatory documentation problems or failure to maintain compliance with the regulatory requirements may result in restrictions on the marketing of a product, revocation of the license, withdrawal of the product from the market, seizures, injunctions, or criminal sanctions. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaboration partners, or our contract manufacturers must supply all necessary documentation in support of an NDA, BLA, MAA or comparable regulatory filing on a timely basis and must adhere to cGMP regulations enforced by the FDA, EEA Competent Authorities and other regulatory authorities through their facilities inspection programs. Some of our contract manufacturers have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our collaboration partners and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent suspension of production or closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could harm our business.

If we, our collaboration partners, or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new pharmaceutical product, withdrawal of an approval, or suspension of production. As a result, our business, financial condition, and results of operations may be harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA or BLA, a supplemental NDA or BLA, a marketing authorization variation application or equivalent foreign regulatory filing, which could result in further delay. The regulatory authorities may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical studies, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

As a pharmaceutical company, we are subject to environmental and safety laws and regulations, including those governing the use of hazardous materials. The cost of compliance with health and safety regulations is substantial. Our business activities involve the controlled use of hazardous materials. Our research and development activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of accidental contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot guarantee that the safety procedures utilized by third-party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and European, U.S. federal and state or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. In the event of an accident or environmental discharge, we may be held liable for any consequential damage and any resulting claims for damages, which may exceed our financial resources and may materially adversely affect our business, results of operations and prospects, and the value of our shares or ADSs.

If we fail to comply or are found to have failed to comply with EEA, FDA and other regulations related to the promotion of our products for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the EEA Competent Authorities, the FDA and other regulatory authorities. If any of our product candidates receives marketing approval, we and any collaboration partner will be restricted from marketing the product outside of its approved labeling, also referred to as off-label promotion. However, physicians may nevertheless prescribe an approved product to their patients in a manner that is inconsistent with the approved label, which is an off-label use. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations regarding off-label promotion. Notwithstanding these programs, the EEA Competent Authorities, the FDA or other government authorities may allege or find that our practices constitute prohibited promotion of our product candidates for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Over the past several years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti- kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

If approved, our product candidates may cause or contribute to adverse medical events that we are required to report to regulatory authorities and if we fail to do so we could be subject to sanctions that would harm our business.

Some participants in clinical trials of our product candidates have reported adverse events. As with all clinical trials, serious or severe adverse events may occur which may compromise the program. The FDA, EEA, and foreign regulatory authority regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events, both during their development and after commercialization, if approved. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA, EEA Competent Authorities, or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

Our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (1) FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) U.S. federal and state fraud and abuse and other healthcare laws and regulations; or (4) laws that require the reporting of true and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These activities also include the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Failure to obtain regulatory approvals in non-U.S. jurisdictions would prevent us from marketing our products outside of the United States.

In the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of MA:

- The Community MA, which is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA, is valid throughout the entire territory of the EEA. The centralized procedure is mandatory for certain types of products, such as medicinal products derived from biotechnology processes, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes and auto-immune and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.
- National MAs, which are issued by the Competent Authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in other Member States through the mutual recognition procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure.

Under the above described procedures, before granting the MA, the EMA or the Competent Authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

In the EEA, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the E.U. Community and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the medicinal product. An E.U. orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. At this time, we do not have an Orphan Medicinal Product Designation for TransCon hGH, or any of our other product candidates.

In the EEA, marketing authorization applications for new medicinal products not authorized in the EU will only be regarded as valid, if they include one of the following: (i) the results of all studies performed and details of all information collected in compliance with a paediatric investigation plan; PIP, agreed with the EMA's Pediatric Committee, or the PDCO, (ii) a decision of the EMA granting a waiver from the obligation to provide the results of studies in the paediatric population in accordance with a PIP, or (iii) a decision by the EMA agreeing to a deferral of the initiation or completion of some or all of the measures set out in the PIP. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the European Union and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension. For orphan-designated medicinal products, the 10-year period of market exclusivity is extended to 12 years. At this time, we have not agreed to a PIP with the PDCO for TransCon hGH, or any of our other product candidates.

Outside the U.S. and the EEA, approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA or EEA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA, EMA, or EEA Competent Authorities does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA, EMA or EEA Competent Authorities. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval, EMA, or EEA Competent Authority. We may not be able to file for regulatory approvals or to do so on a timely basis, and even if we do file we may not receive necessary approvals to commercialize our products in any market.

We may be subject to healthcare laws, regulation and enforcement; our failure to comply with these laws could harm our results of operations and financial conditions.

Although we do not currently have any products on the market, once we begin commercializing our products, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by the U.S. federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate as a commercial organization include:

- the U.S. Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under U.S. federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;
- U.S. false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- U.S. federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the U.S. Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the U.S. federal physician sunshine requirements under the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- state law equivalents of each of the above U.S. federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;
- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in U.S. federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to market our products and adversely impact our financial results.

We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection and information security, and we are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA and, in the EU and the European Economic Area, or EEA, Regulation 2016/679, known as the General Data Protection Regulation, or GDPR. New privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, whether by us, one of our business associates or another third-party, could adversely affect our business, financial condition and results of operations, including but not limited to: investigation costs, material fines and penalties; compensatory, special, punitive, and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; and injunctive relief. Furthermore, these rules are constantly changing; for example, the GDPR came into force in May 2018 changing the European regime. Before that, the US-EU Safe Harbor framework was declared invalid in 2015 and replaced with the US-EU Privacy Shield framework which, along with other methods which permit transfer under European privacy law, are under ongoing review and subject to challenge.

The privacy laws in the EU have been significantly reformed. On May 25, 2018, the GDPR entered into force and became directly applicable in all EU member states. The GDPR implements more stringent operational requirements than its predecessor legislation. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, will require the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the EU, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance including policies, procedures, training and data audit. If we do not comply with our obligations under the GDPR, we could be exposed to fines of up to the greater of €20 million or up to 4% of our total global annual revenue in the event of a significant breach. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations and financial condition.

We cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients', and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. While we attempt to address the associated risks by performing security assessments and detailed due diligence, we cannot assure you that these contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates in the United States and to produce, market and distribute our products in the United States after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in U.S. Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. In addition, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be interpreted and implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recall, replacement, or discontinuance of one or more of our products; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition and results of operations.

In addition, the trend toward managed healthcare in the United States and the changes in health insurance programs, as well as legislative proposals to reform healthcare or reduce government insurance programs, may result in lower prices for pharmaceutical products, including any product that may be offered by us. In addition, any future regulatory change regarding the healthcare industry or third-party coverage and reimbursement may affect demand for any products that we may develop and could harm our sales and profitability. For example, in the United States, the Affordable Care Act was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. The Affordable Care Act, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, established annual fees and taxes on manufacturers of certain branded prescription drugs and medical devices, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point- of-sale discounts, which, through subsequent legislative amendments, will be increased to 70%, starting in 2019, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

We expect that the current presidential administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Since taking office, President Trump has continued to support the repeal of all or portions of the Affordable Care Act. For example, the Tax Cuts and Jobs Act was enacted, which, among other things, removes penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance. Since the enactment of the Tax Cuts and Jobs Act, there have been additional amendments to certain provisions of the ACA. Moreover, on

December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Trump Administration and the Centers for Medicare & Medicaid Services have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken, further reductions to Medicare payments to several types of providers, including hospitals, and an increased statute of limitations period for the government to recover overpayments to providers from three to five years. Recently, there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional U.S. local and national healthcare reform measures will be adopted within and outside the United States in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. The continuing efforts of the U.S. government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability, and the level of taxes that we are required to pay.

Risks Related to Our Intellectual Property

If our intellectual property related to our product candidates is not adequate, we may not be able to compete effectively in our market.

Our success depends in part on our ability to:

- protect our trade secrets;
- apply for, obtain, maintain and enforce patents; and
- operate without infringing upon the proprietary rights of others.

We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that such proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. Any non-confidential disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Where we elect to pursue patent protection on our proprietary technologies, we file, prosecute and maintain international and other national patent applications covering such technologies, including in the United States, Europe, China, and other jurisdictions.

As of December 31, 2018, twenty-four patents have been issued to us in the United States. Seventeen patents are directed to our TransCon technologies and four are directed to TransCon hGH. In addition, as of December 31, 2018, we have approximately 112 issued patents in jurisdictions outside of the United States, at least 65 of which are directed to our TransCon technologies, and 35 of which are directed to our product candidates. As of December 31, 2018, our TransCon hGH is covered by six different patent families and an additional nine patent families covering the auto-injector device, our TransCon PTH is covered by six different patent families and our TransCon CNP is covered by ten different patent families. Most members of these families are applications in an early stage, so it is impossible to make any statements regarding whether or not they will be granted. We are not aware of any challenge to our issued patents, in the United States, Europe or in any other jurisdiction.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc., although we are unaware of any such defects. If we or our current licensors or licensees, or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current licensors or licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may harm our business.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be highly uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other countries. Even if patents do issue on such patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. For example, U.S. patents can be challenged by any person before the USPTO Patent Trial and Appeals Board at any time within the one-year period following that person’s receipt of an allegation of infringement of the patents. Patents granted by the European Patent Office may be similarly opposed by any person within nine months from the publication of the grant. Similar proceedings are available in other jurisdictions, and in the United States, Europe and other jurisdictions third parties can raise questions of validity with a patent office even before a patent has granted. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. For example, a third party may develop a competitive product that provides therapeutic benefits similar to one or more of our product candidates but that has a different composition that falls outside the scope of our patent protection. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is successfully challenged, then our ability to commercialize such product candidates could be negatively affected, and we may face unexpected competition that could have harm our business. Further, if we encounter delays in our clinical trials, the period of time during which we or our collaboration partners could market our product candidates under patent protection would be reduced.

The degree of future protection of our proprietary rights is uncertain. Patent protection may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;

- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or our in-licensed issued patents may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- any patents we obtain or our in-licensed issued patents may not be valid or enforceable; or
- we may not develop additional proprietary technologies that are patentable.

If we or our current licensors or licensees, or any future licensors or licensees, fail to prosecute, maintain and enforce patent protection for our product candidates, our ability to develop and commercialize our product candidates could be harmed and we might not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to our product candidates could harm our business, financial condition and operating results. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering the product candidate, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcomes of proceedings involving assertions of invalidity and unenforceability are unpredictable. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which would render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of, but that we do not believe are relevant to our current or future patents, that could nevertheless be determined to render our patents invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability of our patents covering one of our product candidates, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would harm our business. Moreover, our competitors could counterclaim in any suit to enforce our patents that we infringe their intellectual property. Furthermore, some of our competitors have substantially greater intellectual property portfolios, and resources, than we do.

If we are unable to prevent disclosure of our trade secrets or other confidential information to third parties, our competitive position may be impaired.

In addition to patents, we rely on trade secrets and proprietary know-how. We seek protection, in part, through confidentiality and proprietary information clauses in agreements with our collaboration partners, employees, consultants, outside scientific collaboration partners and sponsored researchers and other advisors. Although we generally require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, and endeavor to execute confidentiality agreements with all such parties, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property or who had access to our proprietary information, nor can we be certain that our agreements with such parties will not be breached. These agreements may not effectively prevent disclosure of confidential and proprietary information and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential and proprietary information. We cannot guarantee that our trade secrets and other confidential proprietary information will not be publicly disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. The failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation could harm our business.

Our commercial success depends significantly on our ability to operate without infringing, violating or misappropriating the patents and other proprietary rights of third parties. Our own technologies may infringe, violate or misappropriate the patents or other proprietary rights of third parties, or we may be subject to third-party claims of such infringement. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. For example, we are aware of several issued patents related to auto-injection devices that may be relevant to our auto-injection device under development with Phillips Medisize A/S (formerly Medicom Innovation Partner A/S); however, we believe that these (i) will expire prior to our product launch, (ii) are invalid, and/or (iii) do not and will not cover our device. We cannot be certain that our product candidates will not infringe existing or future patents. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates or our TransCon technologies. We may not be aware of patents that have already issued that a third party might assert are infringed by our product candidates. It is also possible that patents of which we are aware, but which we do not believe are relevant to our product candidates, could nevertheless be found to be infringed by our product candidates. Nevertheless, we are not aware of any valid issued patents that we believe would prevent us from marketing our product candidates, if approved. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect.

In addition, we and our collaboration partners may face costly and time-consuming intellectual property litigation with the NDA holders and Orange Book patentees of the products in respect of which we seek to obtain FDA approval. Companies that produce branded pharmaceutical products for which there are listed patents in the FDA's Orange Book routinely bring patent infringement litigation against applicants seeking FDA approval to manufacture and market branded and/or generic forms of their products. Accordingly, we may face patent litigation as a result of our submission of NDA applications to the FDA or as a result of submitting an MAA with the EMA.

Intellectual property litigation involves many risks and uncertainties, and there is no assurance that we will prevail in any lawsuit brought against us. Third parties making claims against us for infringement, violation or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Defense of these claims, regardless of their merit, would cause us to incur substantial expenses and, would be a substantial diversion of resources from our business. In the event of a successful claim of any such infringement, violation or misappropriation, we may need to obtain licenses from such third parties and we and our collaboration partners may be prevented from pursuing product development or commercialization and/or may be required to pay damages. We cannot be certain that any licenses required under such patents or proprietary rights would be made available to us, or that any offer to license would be made available to us on commercially reasonable terms. If we cannot obtain such licenses, we and our collaboration partners may be restricted or prevented from manufacturing and selling products employing our technologies. These adverse results, if they occur, could adversely affect our business, results of operations and prospects, and the value of our shares or ADSs.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of contractual or intellectual property lawsuits, USPTO interference or derivation proceedings, European Patent Office oppositions and related legal and administrative proceedings in the United States, Europe and other countries, involve complex legal and factual questions. As a result, such proceedings may be costly and time-consuming to pursue and their outcome is uncertain.

Litigation may be necessary to:

- protect and enforce our patents and any future patents issuing on our patent applications;
- enforce or clarify the terms of the licenses we have granted or may be granted in the future;
- protect and enforce trade secrets, know-how and other proprietary rights that we own or have licensed, or may license in the future; or
- determine the enforceability, scope and validity of the proprietary rights of third parties and defend against alleged patent infringement.

Competitors may infringe our intellectual property. As a result, we may be required to file infringement claims to stop third- party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly, or amended such that they do not cover our product candidates. Moreover, such adverse determinations could put our patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates or to prevent others from marketing similar products.

Interference, derivation or other proceedings brought at the USPTO, may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential collaboration partners. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential collaboration partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for the ADSs could be significantly harmed.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy- Smith Act has transformed the U.S. patent system into a “first to file” system. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaboration partners’ patent applications and the enforcement or defense of our or our collaboration partners’ issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technologies or our ability to enforce our proprietary technologies. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Certain of our employees and patents are subject to German law.

As of December 31, 2018, 61 of our employees work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees are generally subject to the provisions of the German Act on Employees' Inventions, which regulates the ownership of, and compensation for, inventions made by employees. Under this act, we face the risk that we may be required to pay additional compensation for assigned patent rights and disputes can occur between us and our employees or ex-employees pertaining to alleged non-adherence to the provisions of this act that may be costly to defend and consume our management's time and efforts whether we prevail or fail in such dispute. In addition, under the German Act on Employees' Inventions, certain employees may have retained rights to patents they invented or co-invented before October 2009. Although substantially all of these employees have assigned their interest in these patents to us, to the extent permitted by law, there is a risk that the compensation we provided to them may be deemed to be insufficient and we may be required under German law to increase the compensation due to such employees for the use of the patents. In those cases where employees have not assigned their interests to us, we may need to pay compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, our results of operations could be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. Noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Losing our patent rights could enable competitors to enter the market earlier than would otherwise have been the case.

We have not yet registered trademarks for a commercial trade name for any of our product candidates in the United States or elsewhere and failure to secure such registrations could adversely affect our business.

We use various trademark rights in our business, including, Ascendis, and our trade name TransCon. Ascendis is our only registered trademark in the United States. We may not be able to obtain trademark protection in other territories that we consider of significant importance to us. Furthermore, we have not yet registered trademarks for a commercial trade name for any of our product candidates in the United States or elsewhere. During trademark registration proceedings, our trademark applications may be rejected. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties can oppose pending trademark applications and seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing our products under new brands.

As a result of the United Kingdom's referendum on exiting the European Union our trademark is likely to require some form of re-registration in the UK. While this is assumed to be a purely administrative act, we may accidentally not perform all required steps in time which may lead to a lapse of our trademark in the UK.

Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and many countries in Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

We may be subject to claims that we or our employees have misappropriated the intellectual property, including know-how or trade secrets, of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at or engaged by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees, consultants and contractors have used or disclosed such intellectual property, including know-how, trade secrets or other proprietary information. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or access to consultants and contractors. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

Risks Related to Our Ordinary Shares and ADSs

The price of our ADSs may be volatile, and ADS holders may not be able to resell our ADSs at or above the price they paid.

The trading price of our ADSs could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section of this annual report and others such as:

- results from, or any delays in, clinical trial programs relating to our product candidates, including clinical trials for TransCon hGH, TransCon PTH and TransCon CNP;
- our ability to apply our TransCon technologies to therapeutic areas other than endocrinology, including the therapeutic area of oncology;
- our ability to commercialize or obtain regulatory approval for our product candidates, or delays in commercializing or obtaining regulatory approval;
- announcements of regulatory approval or a complete response letter to our product candidates, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements relating to current or future collaborations or joint ventures, including decisions regarding the exercise by our collaboration partners of their options, if any, or any termination by them of their collaborations with us;
- timing and amount of payments to us under our collaborations or joint ventures, if any;
- announcements of therapeutic innovations or new products by us or our competitors;
- announcements regarding the parent drugs that we use in developing our product candidates;
- adverse actions taken by regulatory authorities with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our product candidates;
- any adverse changes to our relationship with any manufacturers or suppliers;
- the success of our testing and clinical trials;
- the success of our efforts to acquire, license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;

- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- European Medicines Agency, or EMA, FDA or other similar regulatory actions affecting us or our industry or other healthcare reform measures in the European Union, United States or in other markets;
- changes in the structure of healthcare payment systems;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of the ADSs;
- sales of ordinary shares and/or ADSs by us, our senior management and board members, holders of the ADSs or our shareholders in the future;
- general economic and market conditions and overall fluctuations in the United States and international equity markets; and
- the loss of any of our key scientific or senior management personnel.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our ADSs. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of the holders of shares or ADSs were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our senior management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

ADS holders do not directly hold our ordinary shares and do not have the rights of a holder of our ordinary shares.

ADS holders are not treated as our shareholders and do not have the rights of a holder of our ordinary shares. Danish law governs shareholder rights. Our depositary, Bank of New York Mellon, is the holder of the ordinary shares underlying our ADSs. The deposit agreement among us, the depositary, and all other persons directly and indirectly holding ADSs, sets out ADS holder rights as well as the rights and obligations of the depositary. In addition, our depositary charges certain fees to holders of our ADSs as set forth in “Item 12 D. Description of Securities Other than Equity Securities –American Depositary Shares.”

ADS holders may not be able to exercise their right to vote the ordinary shares underlying their ADSs.

Holders of ADSs may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement and not as a direct shareholder in the Company. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise of voting rights. Upon timely receipt of notice from us, if we so request, the depositary shall distribute to the holders as of the record date (1) the notice of the meeting or solicitation of consent or proxy sent by us and (2) a statement as to the manner in which instructions may be given by the holders. However, we may not request the depositary to distribute this information which could effectively limit the ability of ADS holders to direct voting of the ordinary shares underlying their ADSs.

ADS holders may instruct the depositary of their ADSs to vote the ordinary shares underlying their ADSs. Otherwise, ADS holders are not able to exercise their right to vote, unless they withdraw the ordinary shares underlying the ADSs they hold. However, they may not know about the meeting far enough in advance to withdraw those ordinary shares. If we ask for instructions from ADS holders, the depositary, upon timely notice from us, will notify the ADS holders of the upcoming vote and arrange to deliver our voting materials to the ADS holders. We cannot guarantee that ADS holders will receive the voting materials in time to ensure that such holders can instruct the depositary to vote the ordinary shares underlying their ADSs or to withdraw the ordinary shares underlying their ADSs so that they can vote such shares directly. If the depositary does not receive timely voting instructions from an ADS holder, the depositary may give a proxy to a person designated by us to vote the ordinary shares underlying ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that ADS holders may not be able to exercise any right to vote, and there may be nothing an ADS holder can do if the ordinary shares underlying their ADSs are not voted as they requested.

An ADS holder may be subject to limitations on the transfer of their ADSs and the withdrawal of the underlying ordinary shares.

ADSs, which may be evidenced by American Depositary Receipts, or ADRs, are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to an ADS holders' right to cancel their ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares. In addition, an ADS holder may not be able to cancel their ADS and withdraw the underlying ordinary shares when such holder owes money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

We have broad discretion to determine how to use the funds raised in our public offerings, and may use them in ways that may not enhance our operating results or the price of our ordinary shares and ADSs.

Our senior management has broad discretion over the use of proceeds from our public offerings, and we could spend the proceeds from those public offerings in ways the holders of shares or ADSs may not agree with or that do not yield a favorable return, if at all. We currently intend to use substantially all of the net proceeds from those public offerings to support the clinical development, regulatory approval and commercial preparations for TransCon hGH, to fund clinical development of our other rare disease endocrinology programs, including TransCon PTH and TransCon CNP, to identify and progress development of new product candidates, including in the therapeutic area of oncology, and for working capital and general corporate purposes. However, our use of these proceeds may differ substantially from our current plans. If we do not invest or apply these proceeds in ways that improve our operating results, we may fail to achieve expected financial results, which could cause the price of the ADSs to decline.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our ordinary shares or ADSs, the price of the ADSs and trading volume could decline.

The trading market for the ADSs may be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical

trials and operating results fail to meet the expectations of analysts, the price of our ADSs would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause the price of our ADSs or trading volume to decline.

If we issue shares or ADSs in future financings, shareholders or holders of ADSs may experience immediate dilution and, as a result, the price of our ADSs may decline.

We may from time to time issue additional shares or ADS at a discount from the trading price of our ADSs. As a result, our shareholders and holders of ADSs would experience immediate dilution upon the issuance of ADSs at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preference share, ADSs or ordinary shares. If we issue shares or securities convertible into shares of our share capital, our ordinary shareholders and holders of ADSs would experience additional dilution and, as a result, the price of our ADSs may decline.

Sales of a substantial number of our ordinary shares or ADSs in the public market could cause the price of the ADSs to fall.

If our existing shareholders or holders of ADSs sell, or indicate an intention to sell, substantial amounts of our ordinary shares or ADSs in the public market, the trading price of our ADSs could decline. Based upon the number of shares outstanding as of March 1, 2019, we have outstanding a total of 42,135,448 ordinary shares. Of those shares, approximately 7,528,823 were owned by current board members, members of our senior management and their respective affiliates, or may otherwise be subject to Rule 144 under the Securities Act. In addition, pursuant to a registration statement on Form F-3 filed in February 2016, 3,706,148 of our ordinary shares are registered for resale by certain selling shareholders, including shareholders that are affiliated with members of our board of directors.

As of December 31, 2018, there were 5,611,629 warrants outstanding. If these warrants are exercised an additional 5,611,629 ordinary shares or ADSs will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional ordinary shares or ADSs are sold, or if it is perceived that they will be sold, in the public market, the trading price of the ADSs could decline. Any sales of securities by these security holders could have a negative effect on the trading price of the ADSs.

Our principal shareholders and senior management own a significant percentage of our shares and are able to exert significant control over matters subject to shareholder approval.

As of March 1, 2019, our senior management, board members, holders of 5% or more of our share capital and their respective affiliates beneficially own approximately 57.2% of our outstanding voting securities. As a result, these security holders have the ability either alone or voting together as a group to determine and/or significantly influence the outcome of matters submitted to our shareholders for approval, including the election and removal of board members, payment of dividends, amendments to our articles of association, including changes to our share capital or any mergers, demergers, liquidations and similar transactions. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares or ADSs that our shareholders or ADS holders may feel are in their best interest as a shareholder or holder of ADSs. In addition, this group of shareholders may have the ability to control our management and affairs. Such control and concentration of ownership may affect the market price of the ADSs and may discourage certain types of transactions, including those involving actual or potential change of control of us (whether through merger, consolidation, take-over or other business combination), which might otherwise have a positive effect on the market price of the ADSs.

The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.

Our corporate affairs are governed by our articles of association and by the laws governing companies incorporated in Denmark, including the Danish Companies Act. The rights of shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. In the performance of its duties, our board of directors is required by Danish law to consider the interests of our company, its shareholders and its creditors. It is possible that some of these parties will have interests that are different from, or in addition to, the interests of our shareholders or the holders of our ADS.

Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated under the laws of Denmark. Substantially all of our assets are located outside the United States. A significant portion of our board members and employees reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the U.S. securities laws of the United States.

The United States and Denmark currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Denmark. To obtain a judgment which is enforceable in Denmark, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim with a court of competent jurisdiction in Denmark. Such party may submit to the Danish court the final judgment rendered by the U.S. court. If and to the extent that the Danish court finds that the jurisdiction of the U.S. court has been based on grounds which are internationally acceptable and that proper legal procedures have been observed, the Danish court should, in principle, give binding effect to the judgment of the U.S. court, unless such judgment contravenes principles of public policy of Denmark. Danish courts are likely to deny the recognition and enforcement of punitive damages or other awards. Moreover, a Danish court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in Denmark are solely governed by the provisions of the Danish Civil Procedure Code.

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or members of our board of directors, our executive board, our senior management or certain experts named herein who are residents of Denmark or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

We qualify as a foreign private issuer and, as a result, we will not be subject to U.S. proxy rules and will be subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

We report under the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act and although we are subject to Danish laws and regulations with regard to such matters and intend to furnish quarterly financial information to the SEC, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, our shareholders and the holders of our ADS may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

Our status as a "foreign private issuer" allows us to adopt International Financial Reporting Standards, or IFRS, accounting principles, which are different than accounting principles under U.S. Generally Accepted Accounting Principles, or U.S. GAAP.

We have adopted and presented our consolidated financial statements in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board. IFRS is an internationally recognized body of accounting principles that are used by many companies outside of the United States to prepare their financial statements; and the SEC recently permitted foreign private issuers such as our company to prepare and file their financial statements in accordance with IFRS rather than U.S. GAAP. IFRS accounting principles are different from those of U.S. GAAP, and SEC rules do not require us to provide a reconciliation of IFRS accounting principles to those of U.S. GAAP. Investors who are not familiar with IFRS may misunderstand certain information presented in our consolidated financial statements. Accordingly, we suggest that readers of our consolidated financial statements familiarize themselves with the provisions of IFRS accounting principles to better understand the differences between these two sets of principles.

As a foreign private issuer and as permitted by the listing requirements of the Nasdaq Global Select Market, we rely on certain home country governance practices rather than the corporate governance requirements of the Nasdaq Global Select Market.

We qualify as a foreign private issuer. As a result, in accordance with the listing requirements of the Nasdaq Global Select Market, we rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of the Nasdaq Global Select Market. For instance, the Listing Rules for the Nasdaq Stock Market, or the Nasdaq Listing Rules, for domestic U.S. issuers require listed companies to have, among other things, a majority of their board members be independent, and to have independent director oversight of executive compensation, nomination of board members and corporate governance matters. As a foreign private issuer, however, while we intend to comply with these requirements, we are permitted to follow home country practice in lieu of the above requirements. Danish law does not require that a majority of our board consist of independent directors or the implementation of a remuneration committee or nominating and corporate governance committee, and our board may thus in the future not include, or include fewer, independent directors than would be required if we were subject to the Nasdaq Listing Rules, or they may decide that it is in our interest not to have a remuneration committee or nominating and corporate governance committee, or have such committees governed by practices that would not comply with Nasdaq Listing Rules. Since a majority of our board of directors may not consist of independent directors if we decide to rely on the foreign private issuer exemption to the Nasdaq Listing Rules, our board's approach may, therefore, be different from that of a board with a majority of independent directors, and as a result, the management oversight of our company could, in the future, be more limited than if we were subject to the Nasdaq Listing Rules. We intend to follow home country practice with regard to, among other things, quorum requirements generally applicable to general meetings of shareholders.

Furthermore, Danish law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in Denmark, thus our practice varies from the requirement of Nasdaq Listing Rule 5620(b). In addition, our shareholders have authorized our board of directors to issue securities including in connection with certain events such as the acquisition of shares or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us, rights issues at or below market price, certain private placements and issuance of convertible notes. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. Accordingly, our shareholders and holders of our ADS may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq requirements.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We qualify as a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We may no longer be a foreign private issuer as of June 30, 2019, which would require us to comply with all of the

periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of January 1, 2020. To maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares or ADSs must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must not be administered principally inside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

We may be a "passive foreign investment company" for U.S. federal income tax purposes for our current taxable year and future taxable years, which could result in adverse U.S. federal income tax consequences to U.S. investors.

Under the Internal Revenue Code of 1986, as amended, the determination of passive foreign investment company, or PFIC, status is fact-specific, and generally cannot be made until after the close of the taxable year in question. Although we do not believe we were a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2018, we may be a PFIC for our current taxable year and future taxable years. A non-U.S. corporation will be considered a PFIC for any taxable year if either (1) at least 75% of its gross income for such year is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during such year) is attributable to assets that produce or are held for the production of passive income. A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). If we are a PFIC for any taxable year during which a U.S. Holder (as defined in "Item 10 E. Additional Information—Taxation—Material U.S. Federal Income Tax Consequences to U.S. Holders") holds ordinary shares or ADSs, the U.S. Holder may be subject to adverse tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of an interest charge with respect to such gain and certain dividends and (iii) compliance with certain reporting requirements. Each U.S. Holder is strongly urged to consult its tax advisor regarding these issues. See "Item 10 E. Additional Information—Taxation—Material U.S. Federal Income Tax Consequences to U.S. Holders."

If a United States person is treated as owning at least 10% of our ordinary shares or ADSs, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. Holder (as defined in "Item 10 E. Additional Information—Taxation—Material U.S. Federal Income Tax Consequences to U.S. Holders") is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares or ADSs, such U.S. Holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). Because our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as "controlled foreign corporations" (regardless of whether we are treated as a "controlled foreign corporation"). A "United States shareholder" of a "controlled foreign corporation" may be required to report annually and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by "controlled foreign corporations," regardless of whether we make any distributions. An individual that is a "United States shareholder" with respect to a "controlled foreign corporation" generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a "United States shareholder" that is a U.S. corporation. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations from starting with respect to your U.S. federal income tax return for the year for

which reporting was due. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries are treated as a "controlled foreign corporation" or whether such investor is treated as a "United States shareholder" with respect to any of such "controlled foreign corporations." Further, we cannot provide any assurances that we will furnish to any "United States shareholders" information that may be necessary to comply with the aforementioned reporting and tax payment obligations. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares or ADSs.

We do not currently intend to pay dividends on our ordinary shares or ADSs, and, consequently, our shareholders' and ADS holders' ability to achieve a return on their investment will depend on appreciation in the price of the ADSs or our ordinary shares.

We do not currently intend to pay any cash dividends on our ordinary shares for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, our shareholders and ADS holders are not likely to receive any dividends on their investment for the foreseeable future. Because we do not intend to pay dividends, our shareholders' and ADS holders' ability to receive a return on their investment will depend on any future appreciation in the market value of our ADSs. There is no guarantee that our ordinary shares or ADSs will appreciate or even maintain the price at which our holders have acquired them.

Investors should be aware that the rights provided to our shareholders and holders of ADSs under Danish corporate law and our articles of association differ in certain respects from the rights that would typically be provided to a shareholder of a U.S. company under applicable U.S. federal and state laws.

Under Danish corporate law, except in certain limited circumstances (which require as a minimum that a proposal for inspection has been supported by a minimum of 25% of the shareholders voting and being present at a general meeting), our shareholders may not ask for an inspection of our corporate records, while under Delaware corporate law any shareholder, irrespective of the size of such shareholder's shareholdings, may do so. Shareholders of a Danish limited liability company are also unable to initiate a derivative action, a remedy typically available to shareholders of U.S. companies, to enforce a right of our company, in case we fail to enforce such right ourselves, other than in certain cases of board member/management liability under limited circumstances. In addition, a majority of our shareholders may release a board member or manager from any claim of liability we may have, including if such board member or manager has acted in bad faith or has breached his/her duty of loyalty and only if a minority of at least 10% of the shareholders represented at the relevant general meeting have opposed the decision, may a shareholder bring a derivative action on behalf of our company. In contrast, most U.S. federal and state laws prohibit a company or its shareholders from releasing a board member from liability altogether if such board member has acted in bad faith or has breached such board member's duty of loyalty to our company. Additionally, distribution of dividends from Danish companies to foreign companies and individuals can be eligible for non-refundable withholding tax, and not all receiving countries allow for deduction. Also, the rights as a creditor may not be as strong under Danish insolvency law, as under U.S. law or other insolvency law, and consequently creditors may recover less in the event our company is subject to insolvency compared to a similar case including a U.S. debtor. In addition, the use of the tax asset consisting of the accumulated tax deficit requires that we are able to generate positive taxable income and can be restricted by future amendments to Danish tax law. Finally, Danish corporate law may not provide appraisal rights in the case of a business combination equivalent to those generally afforded a shareholder of a U.S. company under applicable U.S. laws. As a result of these differences between Danish corporate law and our articles of association, on the one hand, and U.S. federal and state laws, on the other hand, in certain instances, shareholders and ADS holders could receive less protection as an equity holder of our company than they would as a shareholder of a U.S. company.

Holders of our ordinary shares or ADSs may not be able to exercise their pre-emptive subscription rights and may suffer dilution of their equity holding in the event of future issuances of our shares.

Under the Danish Companies Act, our shareholders benefit from a pre-emptive subscription right on the issuance of ordinary shares for cash consideration only and not in the event of issuance of shares against non-cash contribution or debt conversion. Even the shareholders' pre-emptive subscription rights in the event of issuances of shares against cash payment may be disapplied by a resolution of the shareholders at a general meeting of our shareholders and/or the shares or ADSs may be issued on the basis of an authorization granted

to the board of directors pursuant to which the board may disapply the shareholders' pre-emptive subscription rights. Such shares or ADSs may be issued above, or at market value as well as by way of incorporation of available reserves (including premium). In addition, a shareholder may not be able to exercise the shareholder's pre-emptive right on a timely basis or at all, unless the shareholder complies with the Danish Companies Act and applicable laws in the jurisdiction in which the shareholder is resident. Furthermore, the use of pre-emptive subscription rights in relation to future capital increases in our company can be restricted for U.S. residents according to U.S. securities law. As a result, the shareholding or holders of ADSs of such shareholders or ADS holders may be materially diluted in the event shares or ADSs are issued in the future. Shares or ADSs may be issued at a discount to market price in rights offerings provided that the resolution is approved by two-thirds of the votes cast and the share capital represented at the general meeting and in these cases a restriction on the ability to exercise pre-emptive rights may materially dilute the value of the ordinary shares or ADSs held by the shareholder or ADS holder in question. Rights issues may also be carried out by the board of directors according to valid authorizations in our articles of association.

However, our ADS holders in the United States are not entitled to exercise or sell such pre-emptive subscription rights related to the ordinary shares, which they represent unless we register the pre-emptive subscription rights and the securities to which the pre-emptive subscription rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary will not make rights available to ADS holders unless the distribution to ADS holders or both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. Further, if we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case our shareholders and ADS holders will receive no value for these rights.

Item 4 *Information on the Company*

A. History and Development of the Company

We were organized under the laws of the Kingdom of Denmark in September 2006 as a private limited liability company (*Anpartsselskab*, or ApS) and then transformed into a public limited liability company (*Aktieselskab*, or A/S), effective December 17, 2007. In connection with this conversion, our legal name changed from Ascendis Pharma ApS to Ascendis Pharma A/S. We commenced operations in December 2007 in connection with the acquisition of the company that invented our TransCon technologies, Complex Biosystems GmbH.

Our registered office and principal executive offices are located at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark and our telephone number is +45 70 22 22 44. Our agent for service of process in the United States is Ascendis Pharma, Inc. Our website address is www.ascendispharma.com. The information on, or that can be accessed through, our website is not part of and should not be incorporated by reference into this annual report or any other report we file or furnish to the SEC. We have included our website address as an inactive textual reference only. Our ADSs are traded on The Nasdaq Global Select Market under the symbol ASND.

The SEC maintains an internet site at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

For additional information relating to the development of our company, see "Item 4 B. Information on the Company – Business Overview." For additional information relating to the Company's capital expenditures, see "Item 5 A. Operating Results."

B. Business Overview

Overview

We are applying our innovative TransCon technologies to build a leading, fully integrated biopharmaceutical company and develop a pipeline of product candidates with potential best-in-class profiles to address unmet medical needs. We have created a portfolio of potential best-in-class rare disease endocrinology product candidates to address unmet medical needs by utilizing our TransCon technologies with clinically validated parent drugs. We currently have three product candidates in clinical development in rare endocrine diseases and we are working to apply our TransCon technology platform in additional therapeutic areas, including oncology. Additionally, we have developed a pipeline of sustained-release prodrug product candidates through strategic collaborations and we are working with these collaboration partners in the areas of ophthalmology and diabetes.

Our most advanced product candidate, TransCon hGH, is in development as a once-weekly long acting prodrug of recombinant human growth hormone, also referred to as hGH, as a potential treatment for growth hormone deficiency, or GHD. On March 4, 2019, we announced top-line results from the heiGHt Trial. We are also conducting two additional trials with TransCon hGH, the fliGHt Trial, which evaluates TransCon hGH in pediatric subjects previously treated with daily hGH, and the enliGHten Trial, which evaluates long-term safety of TransCon hGH in subjects from both the heiGHt and fliGHt Trials. In September 2018, we completed enrollment in the fliGHt Trial, an open-label trial evaluating TransCon hGH in pediatric subjects with GHD who switched from daily hGH therapy. As a result, more than 300 subjects have now enrolled in the phase 3 TransCon hGH program, which includes the heiGHt, fliGHt and enliGHten Trials. We believe that TransCon hGH may offer a once-weekly therapy for GHD with the potential to improve outcomes compared to currently approved daily hGH. We expect a clinical database lock for the TransCon hGH phase 3 program in pediatric GHD during the third quarter of 2019. Subsequently, we intend to submit a Biologics License Application, or BLA, to the U.S. Food and Drug Administration, or the FDA, for TransCon hGH to treat pediatric GHD in the first half of 2020. We have also conducted a phase 2 clinical trial in adult subjects with GHD that will form the basis of designing future clinical research in adult GHD. If approved, TransCon hGH may reduce the burden of daily treatment by requiring significantly fewer injections, which may improve compliance and treatment outcomes.

We are also using our TransCon technology platform to develop TransCon PTH, a once-daily long-acting prodrug of parathyroid hormone, or PTH, as a potential treatment for hypoparathyroidism, a rare endocrine disorder of calcium and phosphate metabolism. We completed a phase 1 trial in healthy subjects in May 2018, the results of which were consistent with our target product profile for TransCon PTH as a true replacement therapy. In this trial, TransCon PTH showed the predicted pharmacokinetic and pharmacodynamic response, suggesting the ability to normalize serum and urinary calcium levels in patients with hypoparathyroidism. We believe TransCon PTH may provide patients suffering from hypoparathyroidism with a PTH replacement therapy that is designed to fully address all aspects of the disease more than standard of care or currently approved therapies. In June 2018, we were granted Orphan Drug Designation, or ODD, by the FDA for TransCon PTH. ODD is provided to drugs that are intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. We initiated the phase 2 trial in adult subjects with hypoparathyroidism in the first quarter of 2019 with the goal of evaluating different fixed doses of TransCon PTH and a titration regimen for complete withdrawal of standard of care (i.e., calcium and active Vitamin D supplementation), using a ready-to-use prefilled pen device. Our plan for our phase 3 program for TransCon PTH includes incorporating trial sites in the United States, Europe, Australia, Canada, Japan and possibly other Asian countries.

We are also developing TransCon CNP, a long-acting prodrug of C-type natriuretic peptide, as a potential therapeutic option for achondroplasia, the most common form of dwarfism. Currently, there are no medical therapies for achondroplasia approved by the FDA. TransCon CNP utilizes our TransCon technology platform to create a long-acting C-type natriuretic peptide, or CNP, prodrug as a potential therapeutic option for achondroplasia and potentially other skeletal disorders. CNP as a therapeutic approach is supported by extensive preclinical and clinical data. In November 2018, we reported preliminary results from a phase 1 clinical trial in healthy adult subjects, which supported our target product profile for TransCon CNP. In February 2019, we were granted ODD by the FDA for TransCon CNP. Our goal is to develop TransCon CNP as a safe and effective therapeutic option for achondroplasia and potentially other related growth disorders.

In addition to our pipeline of candidates in rare endocrine disorders, in January 2019, we announced that we are establishing oncology as our second independent therapeutic area of focus for our TransCon technologies. Our goal is to improve treatment efficacy while limiting or reducing toxicity by applying TransCon technologies to clinically validated drugs, using our unique algorithm for product innovation. We are conducting preclinical studies within the field of oncology to explore multiple potential product candidates and evaluate systemic as well as localized delivery systems using our TransCon platform.

In November 2018, we announced the formation of VISEN Pharmaceuticals, or Visen, a company established to develop and commercialize our endocrinology rare disease therapies in the People's Republic of China, Hong Kong, Macau and Taiwan, or Greater China. In connection with the formation of Visen, we granted Visen exclusive rights to develop and commercialize certain product candidates based on our proprietary TransCon technologies, including TransCon hGH, TransCon PTH and TransCon CNP, in Greater China for use in all human indications, subject to certain exceptions. As consideration for the rights granted to Visen, we received 50% ownership in the outstanding shares of Visen and concurrently with the rights we granted to Visen, entities affiliated with Vivo Capital and Sofinnova Ventures purchased shares in Visen for an aggregate purchase price of $40 million in cash. We believe Visen supports our strategy to extend our endocrinology rare disease portfolio globally and establish a presence in China in partnership with collaborators who have significant experience and knowledge of the biopharmaceutical opportunity in China. In part because Visen was established in China, we believe Visen will be able to effectively develop and, if approved, market our innovative technologies to address the needs of the local markets in Greater China.

In addition, we have strategic collaborations for TransCon anti-VEGF in the field of ophthalmology, which is partnered with Genentech, and the TransCon peptide program for the treatment of diabetes, which is partnered with Sanofi. We are eligible to receive up to an aggregate of €200 million in development and regulatory milestone payments for products currently being developed under our collaboration agreements, as well as sales-based milestone payments and royalties on future net sales of products.

We believe that the effectiveness of our TransCon technologies is supported by data from our preclinical research and the ongoing clinical programs, including our TransCon hGH, TransCon PTH and TransCon CNP programs, as well as findings from our ongoing development of other product candidates, including our multi-product collaborations with Sanofi and Genentech. We have applied the TransCon technologies in combination with parent drugs with clinical proof of concept using our algorithm for creating products with the potential to be best-in-class in endocrinology rare diseases, and we will continue to apply this algorithm for product selection in new therapeutic areas. We believe this approach may reduce the risks associated with traditional drug development.

Our TransCon technologies enable us to create long-acting prodrug therapies with potentially significant advantages over existing marketed drug products. Our TransCon technologies transiently link an unmodified parent drug to a TransCon carrier via our proprietary TransCon linkers. Our TransCon linkers predictably release an unmodified active parent drug at predetermined rates governed by physiological pH and temperature conditions, supporting administration frequencies from daily to more than every six months. Depending upon the type of TransCon carrier we employ, we can design our TransCon prodrugs to act systemically or locally in areas that are difficult to treat with conventional therapies.

TransCon Product Candidate Pipeline

1. Based on market data and company estimates.
2. Excludes rights granted to VISEN Pharmaceuticals in Greater China.
3. Includes all indications.
4. Based on treatment of ~25% of the U.S. patient population of ~80,000 patients.

In addition to our pipeline of product candidates noted in the figure above, we are conducting preclinical studies in the field of oncology to explore multiple potential product candidates and evaluate systemic as well as localized delivery systems using our TransCon technologies.

When we apply our TransCon technologies to already approved drug compounds, we may benefit from established clinical safety and efficacy data, which we believe increases the probability of success compared to traditional drug development.

We maintain an intellectual property portfolio comprising approximately 136 issued patents and approximately 283 patent applications as of December 31, 2018 with claims directed to composition of matter, process, formulation and/or methods-of-use for our product candidates, including a product-specific device and core TransCon technologies. In addition, each of Genentech and Sanofi have granted us rights that enable us to freely commercialize all improvements to the TransCon technologies developed by such collaboration partners outside of the field identified in their respective collaboration agreements. Other than the rights we have granted to Visen, Sanofi, and Genentech as described herein, we hold worldwide rights to our TransCon technologies and owe no third-party royalty or milestone payment obligations with respect to our TransCon technologies or any of our product candidates. While our TransCon prodrugs may incorporate already approved parent drugs, each of our product candidates is a new molecular entity and is therefore eligible to be granted new intellectual property rights, including new composition of matter patents.

Our Strategy

Our goal is to build a fully integrated biopharmaceutical company by applying our TransCon technology platforms to create a pipeline of proprietary products. Our unique algorithm for product innovation focuses on identifying indications that have an unmet medical need, have a clinically validated parent drug, are suitable to our TransCon technologies, have a clearly differentiated product, have a potential established development pathway and have a large potentially addressable market. Additionally, we form collaborations with market-leading biopharmaceutical companies to develop new products that incorporate our TransCon technologies in therapeutic areas that are of strategic importance.

Using this approach for our endocrinology rare disease franchise, we have obtained positive clinical data for all three of our TransCon product candidates. We are working towards regulatory approval of these candidates in three high value indications, and we are exploring label expansion opportunities, as there are approximately 4,800 orphan drug designations and over 500 of those are for endocrine and metabolic disorders. We expect our near-term therapeutic focus on endocrinology will provide important synergies and a strong foundation for building our commercial infrastructure, including expertise in endocrinology, a concentrated prescriber base, a patient-centric support system, reimbursement and payor expertise and distribution networks.

For the longer term, our aim is to utilize our product innovation algorithm to advance into new therapeutic areas and create sustainable growth through multiple approaches.

In January 2019, we introduced Vision 3x3, our strategic roadmap through 2025 to achieve sustainable growth. Key elements of Vision 3x3 include to:

- obtain regulatory approval for three endocrinology rare disease products: TransCon hGH for pediatric GHD, TransCon PTH for adult hypoparathyroidism and TransCon CNP for achondroplasia;
- create further growth of the company's endocrinology rare disease pipeline through:
  - label expansion programs with the goal of obtaining 9 indications in total; and
  - global clinical reach either directly or through partnerships;
- build an integrated commercial business for the endocrinology rare disease franchise in North America and select European countries, and establish a global commercial presence with partners in other geographic areas; and
- create three independent therapeutic areas, each with a diversified pipeline built on our TransCon technology platform and the company's unique algorithm for product innovation.

TransCon Technologies

Overview

Our TransCon technologies are designed to solve the fundamental limitations of previous approaches applied to extend duration of a drug's action in the body, and to enhance the overall benefit of a given therapeutic. Many drugs suffer from suboptimal pharmacokinetics, short residence time in the body, poor tolerability at the administration site and/or systemic side effects that result from initial drug concentrations that are too high. Frequent administration and poor tolerability negatively impact patient compliance, potentially leading to suboptimal treatment outcomes. To address these issues, several approaches are currently being applied to improve drug characteristics, such as prodrug and sustained release technologies.

Our TransCon technologies combine the benefits of conventional prodrug and sustained release technologies to create new therapies with potentially optimized therapeutic effect, including efficacy, safety and dosing frequency. We believe the technologies can be applied broadly to a protein, peptide or small molecule in multiple therapeutic areas. TransCon molecules have three components: an existing parent drug, an inert carrier that protects it, and a linker that temporarily binds the two. When bound, the carrier inactivates and shields the parent drug from clearance. When injected into the body, physiologic pH and temperature conditions initiate the release of the active, unmodified parent drug in a predictable release manner. Because the parent drug is unmodified, its original mode of action is expected to be maintained. Depending upon the type of TransCon carrier we employ, we can design our TransCon prodrugs to act systemically or locally in areas that are difficult to treat with conventional therapies. In addition to retaining the original mode of action of the unmodified parent drug, we believe this predictable release may improve the likelihood of clinical development success. We refer to our systemic and localized applications of TransCon as individual technologies.

Advantages of our TransCon Technologies

We believe that our TransCon technologies enable multiple therapeutic, drug development, regulatory and intellectual property benefits:

Efficacy

- Same mode of action as parent drug
- Predictable release of unmodified parent drug supporting daily to half-yearly administration
- Enables localized or systemic drug exposure
- Reduces dosing frequency to improve patient adherence and improve overall treatment outcomes
- Dosing and release tailored to desired pharmacokinetic profile and potentially optimize effects of parent drug

Safety and Tolerability

- Same established safety as parent drug with potential enhancements or improvement due to application of TransCon technologies
- Enables switch from continuous infusions to daily or less frequent subcutaneous injections
- High local concentrations of drug while minimizing systemic exposure when using TransCon localized delivery platform may enable efficacious therapy with improved safety profile
- Immunogenic potential, or the ability of a substance to provoke an immune response, comparable to parent drug

Development and Regulatory

- Higher development success rate when incorporating clinically validated parent drugs and potentially expedited development pathways due to leveraging existing knowledge regarding the parent drug

Intellectual Property

- New composition of matter patents

TransCon Technology Components

Our TransCon prodrug product candidates consist of three components: the TransCon linker, the TransCon carrier and a parent drug.

Our broad selection of TransCon linkers, in combination with our systemic and localized carriers, provides us with a powerful and flexible technology platform that we leverage to design potentially best-in-class therapeutics to address unmet medical needs.

TransCon Linkers

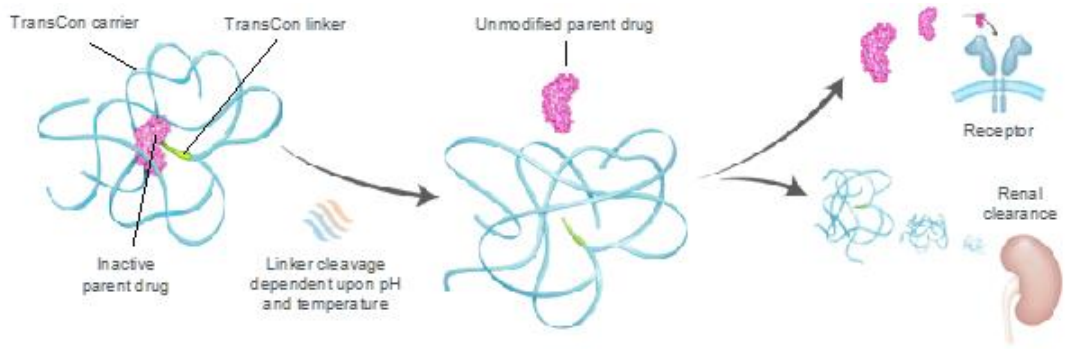
Our TransCon linkers are reversible linkers that enable the transient conjugation of a broad range of therapeutics, including proteins, peptides and small molecules, to our TransCon carriers. We have a large library of TransCon linkers that are applicable to various types of parent drugs, and that can be tailored to achieve half-life extension enabling daily, weekly, monthly and half-yearly dosing, and customize the pharmacokinetic, or PK, profile for each individual product candidate to optimize therapeutic effect. TransCon linkers are self-cleaving through a process

called intra-molecular assisted cleavage, which causes the linker to release the unmodified parent drug. We can tailor the release properties of the linker to a given therapeutic indication and parent drug by modifying the linker structures. We believe the self-cleaving process of our linker avoids many of the shortcomings of conventional prodrug technologies, which often depend on metabolic processes, such as enzymatic degradation, to convert the prodrug into the active drug. The rate of metabolic conversion of prodrugs in these types of processes may differ between patients, and even within different tissues in the same patient. As a result, conventional prodrugs do not offer predictable release of the parent drug. Our TransCon linkers predictably release an unmodified active parent drug at predetermined rates governed by physiological pH and temperature conditions, which are tightly regulated in the body. Consequently, we can design our prodrugs to release the unmodified parent drug at predictable rates.

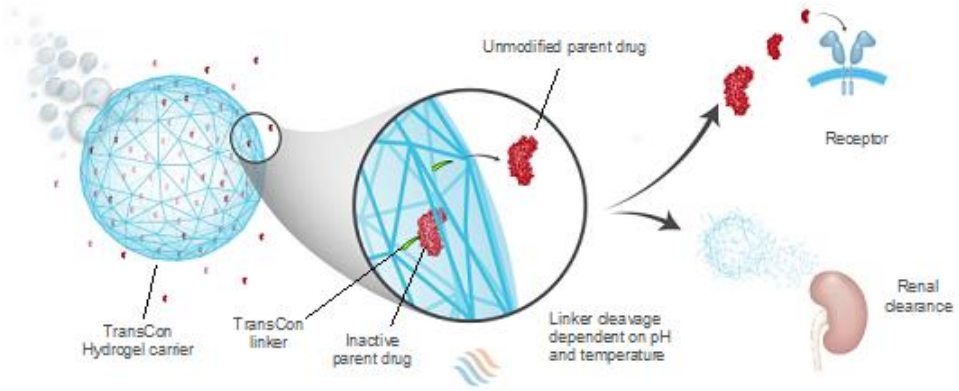
TransCon Carriers

Our TransCon technologies incorporate two carrier platforms that can be used for providing localized or systemic drug exposure. These biocompatible carrier platforms include our TransCon systemic carriers and our proprietary TransCon localized carriers, which are self-eliminating hydrogels. Our carriers inactivate and protect the drug through a shielding effect, which prevents rapid excretion and degradation of the parent drug and may enable benefits that include improved injection site tolerability, reduced systemic adverse effects and low immunogenicity.

- Our TransCon systemic carriers are used for providing systemic drug exposure and are based on soluble compounds such as polyethylene glycol, or PEG, or other natural or synthetic polymers. Prodrugs created using our systemic carriers are readily absorbed into the bloodstream after administration, thus minimizing exposure of the subcutaneous tissue to active drug, which we believe may improve injection site tolerability. Our most advanced product candidates, TransCon hGH, TransCon PTH and TransCon CNP, utilize PEG as a carrier molecule. PEG is widely used to improve the pharmacokinetic or pharmacodynamic properties of marketed therapeutics. Below is an illustration of our systemic carrier:



- Our TransCon localized carriers are being developed to provide either localized or systemic parent drug exposure. Our TransCon hydrogels may be based on PEG, hyaluronic acid or other biopolymers. Our TransCon hydrogel is designed to self-eliminate to soluble, biocompatible molecules after the drug payload has been released. With our collaboration partners, we are developing certain of the TransCon hydrogel carriers to provide both systemic and localized parent drug delivery applications. When applied for localized delivery, the TransCon hydrogel enables the release of parent drug at high local concentrations while minimizing systemic exposure. We believe this may widen the therapeutic window for parent drugs that suffer from significant systemic side effects and facilitate the development of highly efficacious product opportunities that have improved safety and tolerability profiles. Below is an illustration of our hydrogel carrier:



Parent Drug

Our TransCon technologies are applicable across a broad range of therapeutic classes and is currently used to create superior long-acting product candidates based on proteins, peptides and small molecules. By primarily focusing on biological targets that have been clinically validated, we can leverage available knowledge regarding a target's activity. Based on this selective approach, we know what drug levels must be maintained in the body for optimal efficacy and safety, and we can design the release half-life and dosing frequency of our TransCon prodrugs to maintain these levels to achieve the desired pharmacological effect. We move a product candidate into development after it demonstrates a superior profile to such medicines or drugs in animal models that we believe correlate to human clinical experience. Furthermore, based on the established translational relationships between preclinical animal models and clinical efficacy, we believe experimental results generated in validated animal models are highly predictive of clinical results and reduce the development risk of our TransCon prodrugs. This strategy is designed to reduce risk and increase productivity.

This approach has enabled us to generate a pipeline of product candidates to address significant unmet medical needs and to become potential sources of significant revenue for our company. Because our TransCon technologies release an unmodified drug with established clinical safety and efficacy, we believe we may benefit from a higher development and regulatory success rate as compared to development of drug compounds without established clinical data.

TransCon Product Candidates

TransCon Growth Hormone (hGH)

Market Opportunity in GHD

GHD is a serious orphan disease that affects both children and adults. Children with GHD are characterized by short stature, metabolic abnormalities, cognitive deficiencies and poor quality of life. GHD in adults is associated with increased adiposity, or fat mass, as well as psychiatric-cognitive, cardiovascular, muscular, metabolic and skeletal abnormalities. The current standard of care for GHD is daily subcutaneous injections of hGH. Daily therapy with hGH has been shown to increase growth and improve metabolic effects, including reducing adiposity and improving cardiovascular health. These therapies have been shown to be safe and well-tolerated.

Growth hormone-deficient children who are fully in adherence with their daily treatment regimen may achieve a height in adulthood that is comparable to that of their family members and national norms. In therapy-compliant adults with GHD, daily subcutaneous injections of hGH have resulted in improved body composition parameters, bone density, cardiovascular outcomes and quality of life.

Despite the demonstrated benefits of hGH therapy, compliance continues to be a challenge, as patients treated with daily hGH typically receive thousands of injections over the course of many years. Published studies have shown that the majority of patients on a daily hGH regimen are not fully compliant with their daily dosing schedule, and therefore fail to achieve expected treatment outcomes. In a 2011 study 66% of the patients missed more than one injection on average per week, which resulted in significant reductions in the degree of growth in those patients. For caregivers of young children and teenagers who likely have had to endure daily injections of hGH for many years, the problem of needle fatigue – missing injections because of the pain, bruising or other effects of daily treatment – remains an important reason for noncompliance with daily treatment.

Reducing injection frequency is associated with better compliance and may improve height velocity (HV) for patients experiencing poor compliance with daily injections. As shown in the figure below, for patients missing two or more injections per week, there was a clinically relevant reduction in their change in HV standard deviation score, or HVSDS, compared to high-compliance patients. A greater HVSDS indicates more rapid growth:

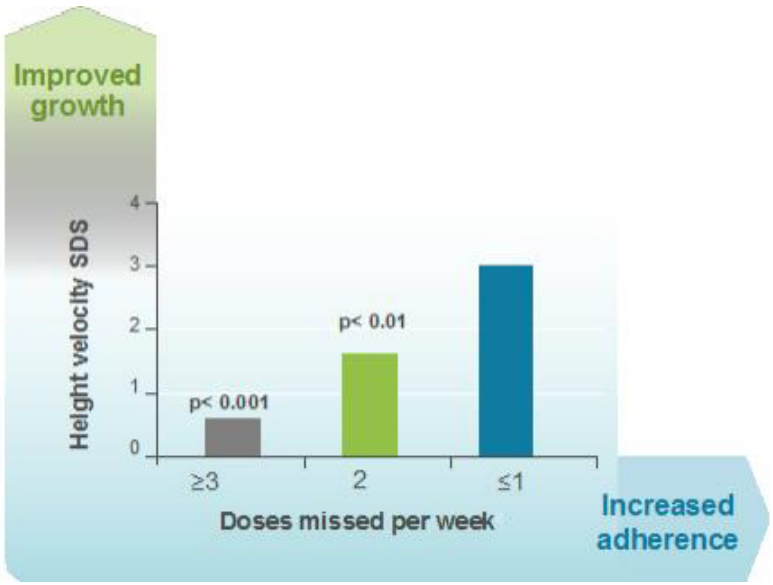


Figure 1. Negative impact of poor compliance on growth response. Patients missing two or more injections per week have a statistically significant reduction in height velocity. A result is considered statistically significant when the p-value, representing the probability that random chance could explain the result, is lower than 0.05.(Cutfield et al, 2011.)

Since the introduction of hGH in 1981, many of the world's largest pharmaceutical companies have developed and now market daily hGH products. All currently marketed hGH products in the United States, Norditropin ® (Novo Nordisk A/S), Humatrope ® (Eli Lilly and Company), Nutropin AQ ® (Genentech), Genotropin ® (Pfizer Inc.), Saizen ® (Merck Serono S.A.), Zomacton ® (Ferring Pharmaceuticals, Inc.) and Omnitrope ® (Sandoz GmbH), contain unmodified hGH and are administered by daily subcutaneous injections. The global market for daily hGH products is dominated by Novo Nordisk, Pfizer, Eli Lilly, Sandoz, Merck KGaA and Roche, which together account for approximately 95% of global market share.

Primary indications for hGH in children are GHD, idiopathic short stature, chronic kidney disease, Prader-Willi syndrome, small for gestational age and Turner syndrome. In adults, primary indications for hGH include GHD and AIDS-induced weight loss. Pediatric indications comprise up to 90% of the total hGH market, of which approximately half is for GHD.

Global annual sales from currently marketed daily hGH injections are estimated at $3.5 billion in 2014. We believe a significant market opportunity exists for a long-acting version of hGH with comparable efficacy, safety and tolerability as daily hGH products. We are developing TransCon hGH as a once-weekly therapy with a target profile designed to have comparable efficacy, safety and tolerability to daily hGH, but with a dosing regimen that could improve adherence and overall health.

Competitive Landscape for Long-Acting Growth Hormone

Since the 1990s, the pharmaceutical industry has employed various approaches to develop long-acting hGH products to reduce the patient burden of daily injections and increase patient compliance with the dosing regimen. These approaches generally fall into two categories: encapsulation and permanent hGH modification:

- Two long-acting growth hormone products using encapsulation technologies have previously received regulatory approval in U.S. and Europe and were subsequently discontinued due to commercial challenges. These include Nutropin Depot ®, formerly marketed by Genentech, and Somatropin Biopartners, developed by LG Life Sciences and Biopartners GmbH. Nutropin Depot was approved in 1999 and later withdrawn; Somatropin Biopartners (LB03002), was approved by the European Medicines Agency (EMA) in 2013, and later withdrawn. These products are associated with nodule formation, erythema, or redness of skin, itching, bruising, as well as pain during and after injection. In addition, high levels of antidrug antibodies have been observed following administration of these drugs to patients. We believe that the lack of market acceptance is a result of the various safety and tolerability issues that tend to arise with encapsulation technologies.
- Modification technologies prolong growth hormone activity in the body by creating analogs of growth hormone through permanent modification of the growth hormone molecule. This modification may alter the molecular size and interaction with the growth hormone receptor and/or change the natural association affinity to endogenous proteins, as well as the distribution in the body. These changes may alter and reduce the efficacy of these drugs compared to unmodified daily growth hormone and may also negatively impact the drug's safety.

There are currently no long-acting growth hormone treatment options available in the United States or Europe. A permanently PEGylated long-acting growth hormone developed by GeneScience Pharmaceuticals Co., Ltd. is available in China and the Somatropin Biopartners product (LB03002), is available in Korea. Genexine Inc., Hanmi Pharmaceutical Co., Ltd., Bolder Biotechnology, Novo Nordisk A/S, and OPKO Health, Inc., are developing long-acting growth hormone analogs based on the permanent modification of growth hormone.

In addition to the currently approved and marketed daily growth hormone therapies, there are a variety of experimental growth hormone therapies in different stages of clinical development by various companies, including GeneScience Pharmaceuticals Co., Ltd., Genexine Inc., JCR Pharmaceuticals Co., Ltd., Novo Nordisk A/S, and OPKO Health, Inc. (in collaboration with Pfizer Inc.) and other global and regional pharmaceutical companies with existing growth hormone franchises.

Our Solution: TransCon hGH

TransCon hGH is a long-acting growth hormone product candidate that is being developed for the treatment of GHD. It is designed to maintain the same mode of action as daily therapies by releasing the same growth hormone molecule as daily therapy. TransCon hGH is composed of an unmodified growth hormone that is transiently bound to a carrier and proprietary linker.

TransCon hGH is essentially inactive when administered. Our technologies are designed to restore full activity of the parent growth hormone when the unmodified growth hormone is released. Growth hormone is predictably released, enabling weekly dosing. We have conducted biopotency assays and generated mass spectrometry profiles demonstrating that the bioactivity and structure of growth hormone released from TransCon hGH is comparable to the growth hormone in marketed growth hormone products administered as daily injections. Importantly, we expect our once-weekly TransCon hGH to have the same mode of action and distribution into key growth hormone -responsive tissues, such as brain, bone, muscle, liver and fat tissue, as the hGH administered from daily injections and endogenous growth hormone. We use daily growth hormone as an active comparator in our clinical studies, allowing us to directly compare the activity of TransCon hGH to daily growth hormone in an identical clinical setting.

TransCon hGH is designed to address the highest priority unmet medical need in growth hormone therapy by reducing the number of injections patients require, while leveraging the over 30-year history of safety and efficacy that has been established with unmodified daily growth hormone products.

Clinical Development of TransCon hGH for Pediatric GHD

In March 2019, we reported top-line results for the heiGHt Trial, in which TransCon hGH was observed to have superior efficacy and comparable safety and tolerability to that of daily hGH. We expect our efficacy and safety database lock for our regulatory filings with the FDA and EMA to occur in the third quarter of 2019. We subsequently intend to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for TransCon hGH to treat pediatric GHD in the first half of 2020.

In October 2017, we initiated an additional phase 3 trial, the fliGHt (switch) Trial, which is designed to evaluate TransCon hGH in subjects who have been previously treated with daily growth hormone. In this single arm open-label trial, subjects would switch from daily growth hormone therapy to weekly TransCon hGH with a primary objective of determining the safety and tolerability of TransCon hGH in subjects with pediatric GHD. At the request of the FDA to evaluate TransCon hGH in children younger than three years, we enrolled subjects younger than three years of age who may be treatment-naïve. We enrolled a total of 146 subjects, completing enrollment in September 2018. We expect to report top-line data for the fliGHt Trial in the second quarter of 2019.

Subjects completing either the heiGHt or fliGHt Trials may also enroll in an open-label extension study, the enliGHten Trial, in which we expect the vast majority of subjects finishing the heiGHt and fliGHt Trials to enroll. The enliGHten Trial is designed to provide long-term safety data in approximately 300 subjects to support the potential future regulatory filings for TransCon hGH. We initiated the enliGHten Trial in 2017 as the first subjects began to roll over from the heiGHt Trial.

Top-line Results from the Phase 3 heiGHt Trial in Pediatric Subjects with GHD

The heiGHt Trial was a randomized, open-label, active-controlled phase 3 registrational trial that enrolled 161 children with GHD who had not previously been treated. Subjects received either once-weekly TransCon hGH (0.24 mg/kg/week) or daily injections of Genotropin ® at 34 µg/kg/day (0.24 mg/kg/week) with a 2:1 randomization. The primary endpoint was annualized height velocity (AHV) at 52 weeks, with a non-inferiority analysis comparing the difference between the two treatment groups. Other key endpoints included AHV at earlier time points, change in height standard deviation scores (SDS) over 52 weeks, change in serum insulin-like growth factor I (IGF-1) and insulin-like growth factor-binding protein 3 (IGFBP-3) levels, change in IGF-1 standard deviation scores and IGFBP-3 standard deviation scores and normalization of IGF-1 standard deviation scores. Two subjects, one from each arm, withdrew from the trial prior to the final visit.

Top-line results showed that once-weekly TransCon hGH was superior to once-daily hGH on the primary endpoint of AHV at 52 weeks. In the primary analysis of the intent-to-treat population using ANCOVA, TransCon hGH was associated with an AHV of 11.2 cm/year compared to 10.3 cm/year for the daily hGH. The treatment difference was 0.86 cm/year with a 95 percent confidence interval of 0.22 to 1.50 cm/year. The AHV for TransCon hGH was significantly greater than the daily hGH (p=0.0088).

The AHV was greater for TransCon hGH than for the daily hGH at each visit, with the treatment difference reaching statistical significance from and including week 26 onward. The incidence of poor responders (AHV < 8.0 cm/year) was 4 percent and 11 percent in the TransCon hGH and daily hGH arms, respectively. All sensitivity analyses completed from the trial support the primary outcome, indicating the robustness of these results.

Results from the trial indicate that TransCon hGH was generally safe and well-tolerated, with adverse events consistent with the type and frequency observed with daily hGH therapy and comparable between arms of the trial. No serious adverse events related to study drug were observed in either arm. No treatment-emergent adverse events leading to discontinuation of study drug were observed in either arm.

Additional Preliminary Analyses from the heiGHt Trial:

- No neutralizing antibodies detected, and low level (<10 percent) of low-titer non-neutralizing antibodies was similar between the two arms
- Height SDS at 52 weeks increased over baseline by 1.05 for TransCon hGH and by 0.94 for the daily hGH, and the treatment difference in height SDS increased at each visit over 52 weeks
- Body Mass Index (BMI) SDS was stable over 52 weeks and was -0.03 for TransCon hGH and -0.40 for the daily hGH at week 52
- Mean hemoglobin A1c values were generally stable over the course of the trial and remained within the normal range for both arms
- Observed peak and trough insulin-like growth factor-1 (IGF-1) SDS values were 1.3 and -0.5 over 52 weeks, respectively, for TransCon hGH compared to an approximate average IGF-1 SDS of 0.0 for the daily hGH at week 52
- In a pre-defined subset of 11 subjects, IGF-1 levels were assessed during week 13 and results were similar to those reported in the TransCon hGH pediatric phase 2 trial
- Consecutive IGF-1 SDS values >2.0 were uncommon (<10 percent of subjects) and IGF-1 SDS >3.0 were rare (<3 percent of subjects)
- Adverse events leading to dose reduction (IGF-1 levels or clinical symptoms) occurred twice in the TransCon hGH arm (representing 1.9 percent) and once in the daily hGH arm (representing 1.8 percent)

The results presented for the heiGHt Trial are consistent with findings from the phase 2 trial, an active-controlled trial which found that TransCon hGH was comparable to daily hGH in 53 treatment-naïve, pre-pubertal children with GHD. The phase 2 trial was designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of TransCon hGH. This 6-month multi-center, randomized, open-label trial compared three dose levels of TransCon hGH (0.14; 0.21; and 0.30 mg GH/kg/week), administered once per week, to Genotropin at 30 µg/kg/day (0.21 mg GH/kg/week), administered as a daily injection. The primary efficacy endpoint was annualized mean height velocity at six months. Mean annualized height velocities among the three dosing levels administered weekly were 11.9 cm for the 0.14 mg/kg/week dose, 12.9 cm for the 0.21 mg/kg/week dose, and 13.9 cm for the 0.30 mg/kg/week dose, which were comparable to 11.6 cm for the active comparator, daily injections of Genotropin at a 0.21 mg/kg/week dose.

Proprietary Auto-injector Development

As part of our effort to improve treatment compliance among children with GHD, we are developing a state-of-the-art auto-injector for the administration of TransCon hGH. We are planning to introduce this in the enliGHten Trial in the second quarter of 2019 and to make it available to patients in conjunction with a potential commercial launch. The easy-to-use device has a single, low-volume injection for the majority of patients of less than 0.6 mL and requires a small, 31-gauge needle that is only 4 millimeters in length, which is comparable to needles used to administer daily hGH. The device provides for room temperature storage, includes an empty-all design and is expected to last for at least four years. We have conducted human factor studies in more than 100 subjects and incorporated the findings into the design of our auto-injector. We are also working on strategies that will enable the auto-injector to integrate with the digital healthcare system, including Bluetooth connectivity features to allow for easy tracking of dosing compliance over time.

Figure 2. Our state-of-the-art auto-injector is designed to improve treatment compliance for children with GHD.

Clinical Development of TransCon hGH in Adults

We have previously conducted trials of TransCon hGH in adults and intend to pursue development of TransCon hGH in adult GHD. We have completed several phase 1 trials in healthy adult subjects.

In September 2011, we reported data following the completion of a phase 2, European, multi-center, multiple dose, open-label, active-controlled, study to examine the safety, tolerability, pharmacokinetics and pharmacodynamics in 37 adult male and female subjects with GHD.

In this study, serum levels of free hGH and TransCon hGH increased proportionally with the administered dose. The maximum serum concentration of hGH released from TransCon hGH was comparable to the levels achieved by the corresponding amount of hGH given as daily injections. The hGH profiles during Week 4 following weekly subcutaneous administration of TransCon hGH or daily subcutaneous administration of Omnitrope ® (0.006 mg hGH/kg/day, equivalent to 0.04 mg hGH/kg/week) demonstrated good dose proportionality between TransCon hGH dose groups, with peak serum concentrations of hGH being comparable between dose matched TransCon hGH and daily hGH (0.04 mg GH/kg/week).

TransCon hGH also elicited an IGF-1 response that was similar to the IGF-1 response of the same cumulative dose of hGH administered as daily injections over a week. Importantly, the IGF-1 response at Week 1 and Week 4 were similar and without significant accumulation.

In addition to demonstrating similar maximum hGH and resulting IGF-1 concentrations when administered at the same cumulative weekly dose, the exposure to hGH and IGF-1 over one week, as judged by AUC, or Area-Under-the-Curve, was similar between TransCon hGH and daily hGH.

In this study, adverse events were comparable to the incidence and type generally expected when hGH is administered to adults with GHD. Only mild and transient injection site reactions were observed across all treatment groups with no difference between treatment groups, including daily hGH.

No treatment-emergent anti- hGH antibody formation was observed during this multiple-dose study. Importantly, we did not observe any injection site lipoatrophy following repeated injections of TransCon hGH. We believe the PK and pharmacodynamics, or PD, data gathered in our phase 2 multi-dose study in adult subjects supports the desired once-weekly dosing regimen and confirms the favorable safety profile of TransCon hGH previously observed in phase 1 studies.

Future Development Plans

We are currently evaluating clinical development plans for TransCon hGH in adult GHD and additional pediatric indications, and we intend to initiate follow-up clinical trials in the future. We are also considering other potential indications for TransCon hGH where a long-acting hGH therapy may offer a best-in-class option for patients with rare growth disorders.

We currently retain commercial rights to TransCon hGH outside of rights granted to VISEN Pharmaceuticals in Greater China, and may consider forming strategic alliances, creating joint ventures or entering into licensing arrangements with third parties in key geographies where we believe a collaboration partner can aid in the development, regulatory approval and commercialization of TransCon hGH.

TransCon PTH

Market Opportunity in Hypoparathyroidism

Hypoparathyroidism, or HP, is a rare endocrine disorder characterized by deficient or absent parathyroid hormone, or PTH, affecting approximately 80,000 patients in the United States. The most common cause in approximately 75% of cases is inadvertent removal or damage to the parathyroid tissue during neck surgery. Patients with HP cannot adequately regulate calcium and phosphate metabolism and suffer from low calcium and elevated phosphate levels in the blood. The condition results in a diverse range of physical, cognitive and emotional symptoms, including psychiatric disorders, depression, basal ganglia calcifications, lenticular and arterial calcifications. Sustained hypocalcemia manifests clinically as perioral numbness, paresthesias, “brain fog,” and carpopedal muscle spasms, in addition to the serious and potentially life-threatening laryngeal spasm, tetany, and seizures.

PTH controls serum calcium via several mechanisms. PTH acts to release calcium from the skeleton and in the kidney to reabsorb calcium from the urine. In addition, PTH facilitates the conversion of 25 hydroxyvitamin D to the active form, which in turn acts on the intestines to increase calcium absorption. Through these primary pathways, calcium homeostasis is maintained.

Standard of care (SoC) today for HP patients primarily consists of oral calcium and active vitamin D supplementation. However, since PTH is not present at the kidney to facilitate calcium reabsorption from the urine, the goal of SoC is to maintain serum calcium (sCa) levels just below or within the lower part of the normal range (8.5-10.5 mg/dL, or 2.125-2.625 mmol/L), and thereby limit as much as possible the damage from excess urinary calcium. Nonetheless, SoC frequently leads to significant sCa fluctuations accompanied by symptomatic hyper- or hypocalcemia. ISOC with calcium and active vitamin D have been shown to contribute to the risk of renal disease.

HP also poses a high burden on the healthcare system despite current standard of care. For example, one survey of 374 patients showed that 72% experienced more than 10 symptoms in the preceding 12 months, with symptoms experienced for a mean of 13 ± 9 hours a day. Patients often experience decreased quality of life. Other studies showed that 79% of HP cases require hospitalizations and that patients with the disorder results have a four-fold increase in the risk of renal disease compared to healthy controls.

In 2015, Natpara, PTH(1-84), was approved for once-daily subcutaneous injection as an adjunct to vitamin D and calcium in patients with hypoparathyroidism. Natpara has not demonstrated an ability to reduce incidences of hypercalcemia, hypocalcemia or hypercalciuria relative to conventional therapy in treated patients. Teriparatide, PTH(1-34), approved since 2002 for the treatment of osteoporosis, has sometimes been used for treatment of hypoparathyroidism using multiple daily injections, despite not being approved for this indication. Clinical research conducted by the NIH of subjects receiving continuous exposure to PTH(1-34), administered by an infusion pump, has demonstrated simultaneous normalization of sCa and urinary calcium, as well as normalization of bone turnover.

Our Solution: TransCon PTH

TransCon PTH is designed as a novel long-acting replacement therapy for parathyroid hormone, or PTH, dosed once-daily to achieve and maintain a steady concentration of PTH in the bloodstream within the normal range, at levels similar to those observed in healthy individuals. TransCon PTH is designed to restore physiologic levels of PTH 24 hours per day, thereby more fully addressing all aspects of the disease including normalizing serum and urinary calcium and serum phosphate levels. Pharmacokinetic data from our phase 1 trial of TransCon PTH in healthy subjects demonstrated a half-life of approximately 60 hours, supporting an infusion-like profile with daily administration. This half-life is a substantial increase compared to PTH(1-34) and PTH(1-84), both of which have half-lives of only a few hours after subcutaneous administration to humans.

With once-daily dosing, we believe this substantial half-life extension of PTH could more closely reflect the physiological levels of PTH observed in healthy individuals and maintain blood calcium levels and normalize urinary calcium excretion, an improvement over what is currently feasible with existing approved therapies. Pharmacokinetic data from multiple ascending dose (MAD) cohorts in our phase 1 trial of TransCon PTH in healthy subjects demonstrated an infusion-like profile. By providing steady levels of PTH in the physiological range, we believe TransCon PTH can address the fundamental limitations of short acting PTH molecules, such as Natpara, or PTH(1-84), and Forteo, or PTH(1-34) and become a highly differentiated therapy for HP.

Development of TransCon PTH

In May 2018, we completed a phase 1 randomized, single and multiple ascending dose trial to evaluate the safety tolerability, pharmacodynamics and pharmacokinetics of TransCon PTH in healthy adults. Primary objectives of the trial included assessing the safety and tolerability of single and 10 multiple daily doses of TransCon PTH in healthy adults. Secondary objectives of this trial included evaluation of pharmacodynamics, including serum calcium, down regulation of endogenous PTH(1-84), and bone markers; pharmacokinetics following single and multiple daily doses of TransCon PTH; assessment of whether TransCon PTH treatment affects fractional excretion of urinary; and, incidence of anti-PTH and anti-PEG antibodies.

Data from SAD and MAD cohorts of TransCon PTH led to sustained and dose-dependent elevations of serum calcium with low inter-subject variability. This dose-dependent response and low inter-subject variability suggests the ability to titrate and individualize dosing in patients. Following 10 repeated doses, free PTH exhibited a flat, infusion-like profile with low inter-patient variability. TransCon PTH was also observed to have the expected effects on renal calcium reabsorption based on fractional excretion and down regulation of endogenous PTH(1-84).

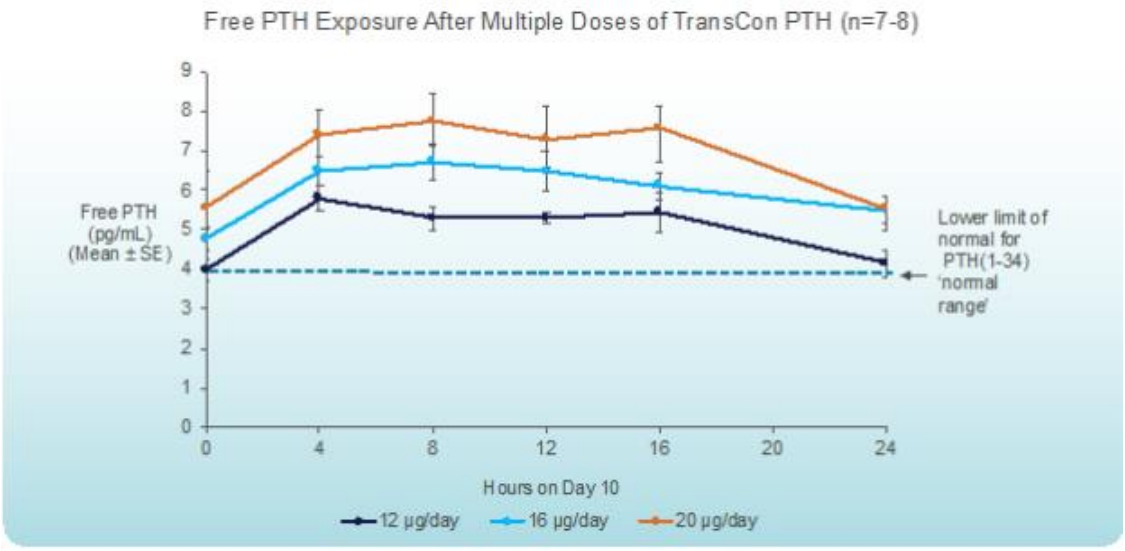


Figure 1: TransCon PTH daily dosing for10 days of 12, 16 and 20 µg per day (n=7-8 per group). TransCon PTH daily dosing for 10 days provided a flat infusion-like profile with a low PTH peak-to-trough ratio at day 10.

In addition, the TransCon PTH PK translated into a predictable sCa response, suggesting the ability to titrate patients with HP into the normal calcemic range, consistent with preclinical data.

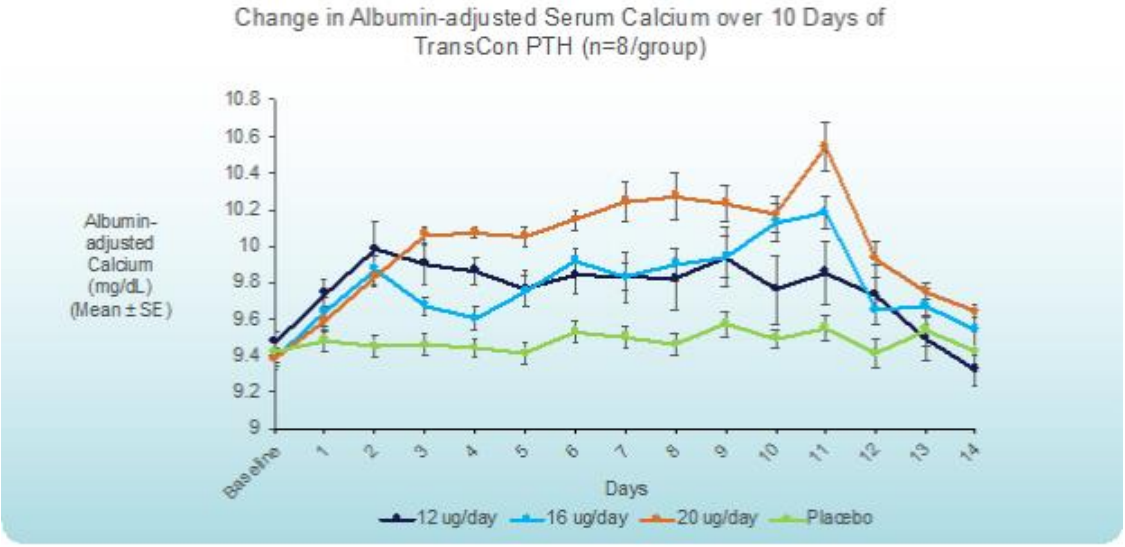


Figure 2: Serum calcium over 10 days of TransCon PTH (n=8/group). TransCon PTH daily dosing for 10 days provided a dose-dependent increase of serum calcium.

TransCon PTH also demonstrated the expected effect on renal calcium reabsorption, and maintained a normal fractional excretion of calcium, even in the presence of hypercalcemia, predicting control of both serum and urine calcium.

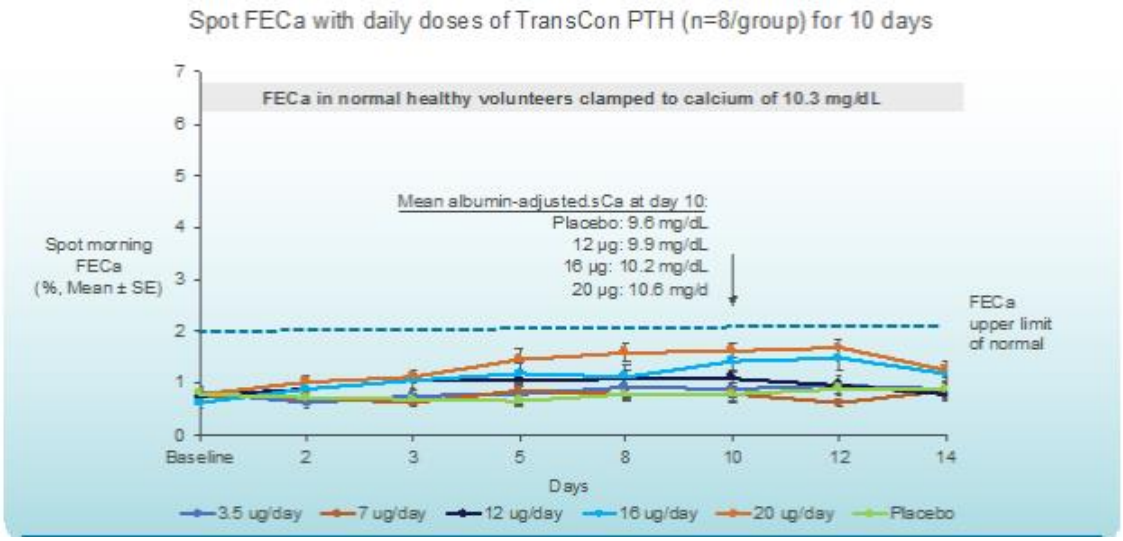


Figure 3: Control of urinary calcium with multiple doses of TransCon PTH 100 µg (n=8/group). Despite serum calcium at 11 mg/dL, fractional calcium excretion remained normal and below the 6.5% range reported for healthy subjects clamped to serum Ca of 10.3 mg/dL[2], reflecting potent renal calcium reabsorption.

The final results of the phase 1 trial were consistent with our target product profile for TransCon PTH, showing the predicted pharmacokinetic and pharmacodynamic response, and suggesting the ability to normalize serum and urinary calcium levels in patients with hypoparathyroidism. We believe our TransCon PTH may provide patients suffering from hypoparathyroidism with a PTH replacement therapy that is designed to fully address all aspects of the disease more than standard of care or currently approved therapies.

In June 2018, we were granted Orphan Drug Designation, or ODD, by the FDA, for TransCon PTH. The FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. We plan to conduct a phase 2 trial to provide experience with different dosing regimens of TransCon PTH, and with titration of calcium and active Vitamin D supplementation. In February 2019, we filed an investigational new drug (IND) application with the FDA for initiation of PaTH Forward, a global phase 2 trial designed to evaluate the safety, tolerability and efficacy of TransCon PTH in adult subjects with hypoparathyroidism (HP). The trial will also evaluate a titration regimen for the complete withdrawal of standard of care (i.e., active vitamin D and calcium supplements) using a ready-to-use prefilled pen device. Our plan for our phase 3 program for TransCon PTH includes incorporating trial sites in the United States, Europe, Australia, Canada, Japan and possibly other Asian countries.

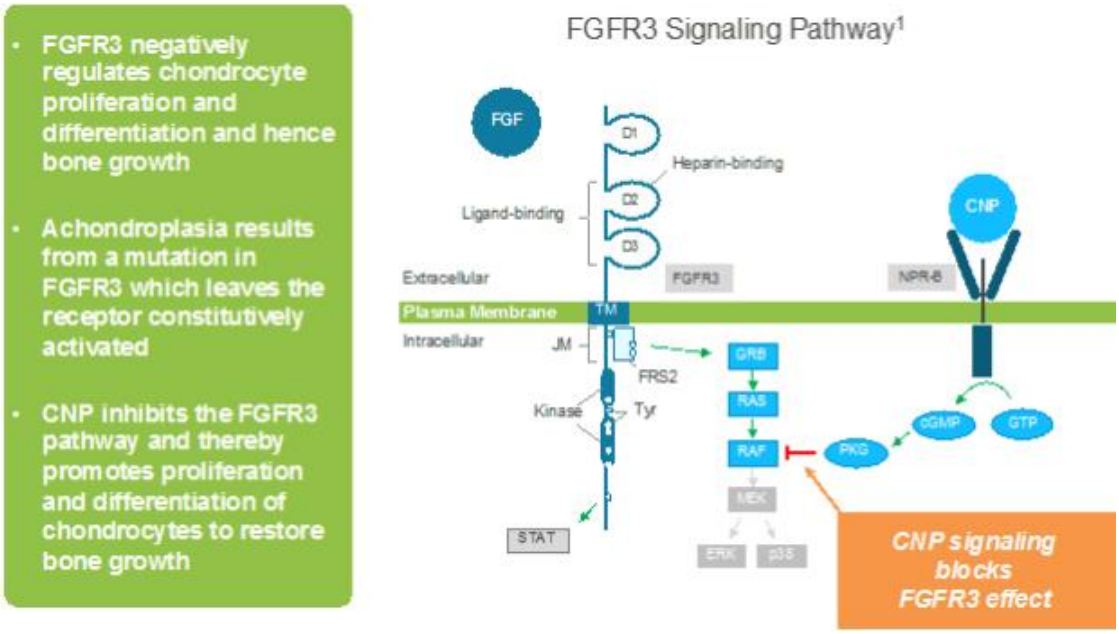
TransCon CNP

Market Opportunity in Achondroplasia

Achondroplasia is the most common form of dwarfism, occurring in about 1 in 10,000 to 30,000 newborns or approximately 250,000 worldwide. Achondroplasia results in severe skeletal complications and comorbidities, including spinal stenosis due to premature fusion of the foramen magnum, sleep apnea, and chronic ear infections. Patients often face multiple surgeries to alleviate its many complications. There are currently no FDA-approved pharmacological treatments for achondroplasia.

Achondroplasia is caused by an autosomal dominant activating mutation in fibroblast growth factor receptor 3, or FGFR3 that leads to an imbalance in the effects of the FGFR3 and C-type natriuretic peptide (CNP) signaling pathways. In achondroplasia, mutations in FGFR3 result in constitutive activation, suppressing the proliferation and differentiation of chondrocytes resulting in improper cartilage to bone conversion in the growth plate.

Preclinical and clinical data show that the CNP pathway stimulates growth and increased CNP helps to counteract the effects of the FGFR3 mutation downstream. Administration of CNP to patients with achondroplasia and in animal models of achondroplasia has been found to stimulate growth.



1 Adapted from Current Opin Pediatrics 2010; 22:516-523.

Figure 1. The role of a defect in the FGFR3 signaling pathway in the development of achondroplasia is well understood.

Our Solution: TransCon CNP

Endogenous CNP has an extremely short half-life of only approximately two minutes. Vosoritide, a CNP analogue, has been developed to provide better stability of CNP, and has a half-life of about 20 minutes. However, short-acting CNP analogues that result in high Cmax levels may cause adverse cardiovascular effects. As achondroplasia is caused by an FGFR3 mutation that chronically inhibits growth, we expect a more constant CNP exposure to correlate with better therapeutic outcomes.

TransCon CNP is a long-acting C-type natriuretic peptide designed to provide sustained CNP exposure at therapeutic levels as a well-tolerated and convenient once-weekly dose. It is being developed for the treatment of children with achondroplasia. TransCon CNP is designed to provide effective shielding of CNP from neutral endopeptidase degradation in subcutaneous tissue and the blood compartment, minimize binding of CNP to the NPR-C receptor to decrease clearance and reduce binding of CNP to the NPR-B receptor in the cardiovascular system to avoid hypotension. It releases CNP, which is small enough in size to allow effective penetration into growth plates.

Our preclinical development demonstrated that combining TransCon technologies with CNP creates a prodrug that slowly releases unmodified CNP resulting in a half-life in primates of approximately 72 hours, representing a more than 1,000-fold longer half-life than native CNP. This is a substantial increase compared to both wild-type CNP and vosoritide, which have half-lives of approximately 2 and 20 minutes, respectively. We believe this will enable weekly administration of TransCon CNP, avoiding the high concentrations of CNP that may cause adverse cardiovascular effects, while maintaining efficacious CNP levels. The goal is to provide a safer and more efficacious therapy for achondroplasia than daily administration of short-acting CNP analogues.

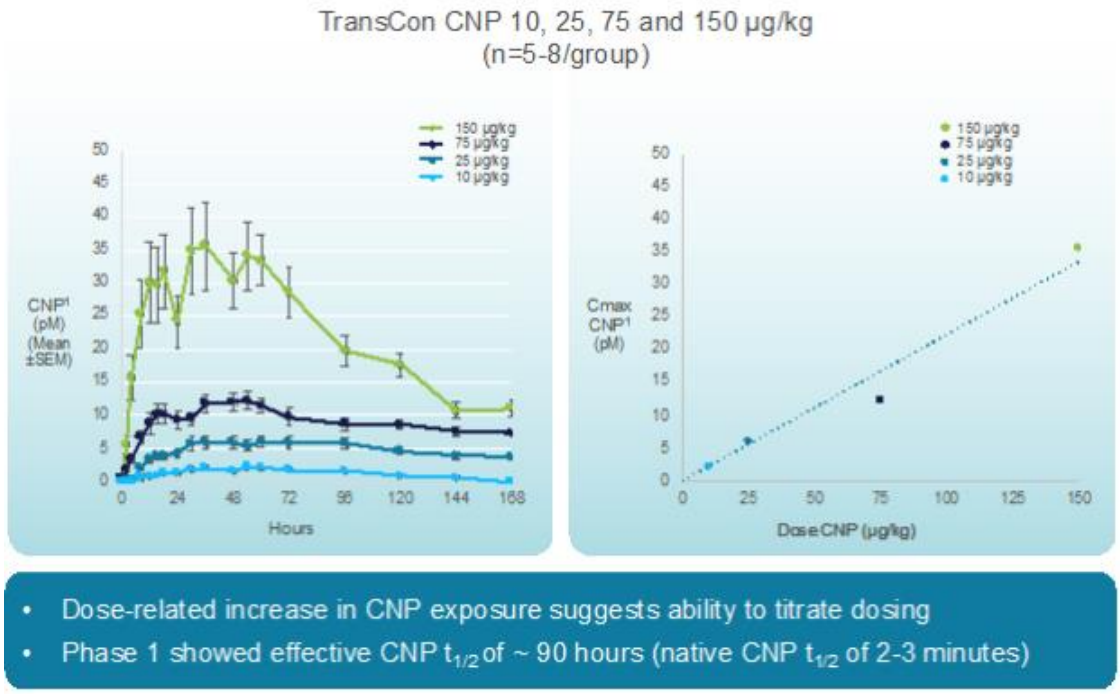
Additional preclinical studies of TransCon CNP support this target product profile and have demonstrated a dose-dependent effect on growth without adverse cardiovascular effects in therapeutic relevant doses. We completed a juvenile primate study comparing weekly TransCon CNP to an approximately three times higher cumulative daily dose of a synthesized molecule with the same amino acid sequence as vosoritide. Based on data from this study, both TransCon CNP and the synthesized molecule with the same amino acid sequence as vosoritide demonstrated a trend of increased bone growth over vehicle-treated monkeys.

Clinical Development of TransCon CNP

In November 2018, we reported preliminary results from a phase 1 trial of TransCon CNP in healthy adult subjects, which supported our target product profile for TransCon CNP. In this phase 1, double-blind, randomized, placebo-controlled trial, 45 healthy adult subjects were enrolled. Five doses of TransCon CNP were tested sequentially, beginning with the lowest dose: 3, 10, 25, 75 and 150 micrograms per kilogram. Up to 10 subjects in each dose cohort were randomized to receive TransCon CNP or placebo in a 4:1 ratio. After each cohort completed dosing, a Data Safety Monitoring Board reviewed the blinded data to approve escalation to the next higher dose. The primary endpoint was frequency of adverse events after administration of TransCon CNP. Secondary endpoints included additional safety parameters, tolerability and pharmacokinetics.

The results showed TransCon CNP provided continuous exposure to CNP with a pharmacokinetic profile designed to provide efficacy with once-weekly dosing. No serious adverse events were reported in the trial and TransCon CNP was generally well tolerated at doses up to 150 microgram/kilogram. Mean orthostatic changes in vital signs appeared unrelated to TransCon CNP exposure and were consistent between placebo and TransCon CNP cohorts. Mean resting blood pressure and heart rate were unchanged from pre-dose at all time points, in all cohorts. Injections were well tolerated in all dose cohorts with no reported injection-related adverse events. These results highlight the potential for TransCon CNP to have a significant impact on patients' lives, not only affecting height but also addressing the many comorbidities associated with achondroplasia.

We expect to initiate a phase 2 trial of TransCon CNP in pediatric subjects with achondroplasia in the third quarter of 2019. In parallel, we are conducting the ACHieve Study, a natural history study designed to gain insight into the experience of pediatric patients with achondroplasia. ACHieve will study growth velocity, body proportionality, and comorbidities over time of children with achondroplasia up to 8 years old. No study medication will be administered. In February 2019, we were granted orphan drug designation by the FDA for TransCon CNP. Our goal is to develop TransCon CNP as a safe and effective therapeutic option for achondroplasia and potentially other related growth disorders.



1 CNP measured as CNP-38.

Figure 2. Pharmacokinetic results for TransCon CNP 10, 25, 75 and 150 microgram/kg administered as a once-weekly subcutaneous injection are presented. As shown, a dose-related increase in CNP exposure was seen and the effective half-life of CNP was found to be approximately 90 hours, which is significantly higher than the half-life of native CNP (approximately two minutes).

TransCon for Oncology

Market Opportunity in Oncology

Cancer remains a major unmet medical need and the incidence of many cancer types continues to rise. Improved understanding of the cellular and molecular mechanisms involved in anti-tumor immune responses has fueled the rapid growth of immuno-oncology therapeutics. In particular, immune checkpoint inhibitors, such as anti-PD-1, anti-PD-L1 and anti-CTLA-4 antibodies, have provided new therapeutic options for patients who did not respond to previous therapies. Supported by these and other advancements, oncology is now the largest therapy class in terms of revenue in pharmaceutical industry, with worldwide prescription drug and over-the-counter sales of $94 billion in 2016 with projected growth to $192 billion in 2022.

Despite these recent advances, there is still a high unmet medical need for new treatment options, as many patients do not respond to current therapies and the efficacy is often limited by toxicities that result in dose reductions or treatment discontinuations. One approach to minimizing adverse events while retaining or improving efficacy is to create product candidates with longer half-lives, allowing for more consistent circulating drug levels and less frequent administration than the corresponding wild-type molecules. Another approach is intratumoral injection, which is to directly administer a drug to the tumors. Early clinical results for intratumoral treatment of cutaneous tumors are encouraging, but the frequent administration of short-acting molecules to difficult-to-access tumors is often impractical. Increased and prolonged therapeutic activity in tumors has the potential to improve outcomes in patients with suboptimal responses to current therapies.

Our Solution: TransCon Technologies for Oncology

Our TransCon technologies can be designed for sustained systemic or localized, intratumoral administration to provide durable and potent anti-tumor effects. TransCon product candidates have the potential to facilitate all the critical steps of the cancer immunity cycle that lead to eradication of malignant cells. TransCon product candidates can be designed to optimize the efficacy of clinically validated therapies while limiting adverse effects. For example, many therapies are administered at the maximum tolerated dose, and the ability to deliver therapies directly to the tumor may improve tolerability as well as improving efficacy, as high local drug concentration can be achieved, while maintaining low systemic exposure. In addition, TransCon product candidates are designed for sustained release, so they may allow for less frequent dosing, enabling treatment of tumor types that cannot be injected frequently.

We have conducted nonclinical studies that have found that TransCon oncology product candidates can slowly release immune-oncology agents, highlighting their potential to enhance the immune system to attack malignant tumor cells. In a syngeneic mouse tumor model, the TransCon TLR agonist resulted in potent inhibition of tumor growth following a single intratumoral injection.

Development of TransCon Oncology Products

Our goal is to improve treatment efficacy while limiting or reducing toxicity by applying TransCon technologies to clinically validated drugs, using our unique algorithm for product innovation. We are conducting preclinical studies within the field of oncology to explore multiple potential product candidates and evaluate systemic as well as localized delivery systems using our TransCon technologies. We are evaluating multiple TransCon product candidates in preclinical research studies for the treatment a variety of tumor types. Examples of TransCon product candidates under evaluation include stimulators of innate and adaptive immunity, as well as modulators of the tumor environment. We are exploring systemic and intratumoral administration both as a monotherapy and as a component of combination regimens.

Strategic Collaborations

We also engage in strategic collaborations to further leverage our TransCon technology platforms in certain geographies with market-leading biopharmaceutical companies. These collaborations aim to further monetize our TransCon technology platforms beyond our internal, wholly-owned product candidates, particularly into therapeutic areas where we believe a partner may have more expertise, capability and capital. In addition, we may choose to pursue a collaboration to develop and market our internal, wholly-owned product candidates in geographic markets outside our core focus of the United States and Europe.

Outside rare endocrine disorders, we currently have multi-product collaborations with market-leading pharmaceutical companies who are applying our TransCon technologies to build a pipeline of sustained-release prodrug product candidates. These include collaborations with Genentech in the field of ophthalmology and Sanofi in the field of diabetes. We are eligible to receive up to an aggregate of €200 million in development and regulatory milestone payments for products currently being developed under our collaboration agreements, as well as sales-based milestone payments and royalties on future net sales of such products.

Sanofi: TransCon Peptides

Overview and Market Opportunities

Together with our collaboration partner, Sanofi, we are developing TransCon peptides for the treatment of diabetes, a major cause of morbidity and mortality across the world. The current standard of care for diabetes often includes daily injections. Compliance and adherence to such regimens are poor due to the burden of daily injections. According to the WHO, diabetes is a global epidemic with 347 million people worldwide having diabetes. The diabetes market is expected to increase due in part to increasing obesity rates.

Our Solution: TransCon Peptides

With our collaboration partner, Sanofi, we are researching and developing long-acting TransCon prodrugs for the treatment of diabetes. Our TransCon prodrugs are designed to enable safe and efficacious levels of unmodified drug and provide extended dosing profiles. Sanofi is currently evaluating the safety and efficacy of various TransCon prodrug candidates for the treatment of diabetes.

Strategic Collaboration with Sanofi

In December 2010, we entered into a strategic collaboration agreement with Sanofi under which we assigned to Sanofi certain diabetes-related patent rights, and granted to Sanofi an exclusive, worldwide, royalty-free license to research, develop, make and commercialize (1) products based on the TransCon technologies and any combination of glucagon-like-peptide-1, or GLP-1, glucagon and insulin to treat any diseases in humans or animals, or (2) any other product developed by Sanofi incorporating our TransCon technologies, other technology covered by the assigned patents or other improvements to our TransCon technologies or the foregoing products, to treat diabetes in humans or animals. During the term of the agreement, we are prohibited from engaging in any research, development or commercialization activities related to certain specified products. In addition, we granted Sanofi a non-exclusive, royalty-free license to research, develop, manufacture and commercialize products other than those based on the TransCon technologies and any combination of GLP-1, glucagon and insulin that are developed by Sanofi incorporating our TransCon technologies, other technology covered by the assigned patents or other improvements to our TransCon technologies or the foregoing products for the treatment of certain diabetes-related metabolic disorders and obesity in humans and animals, so long as, for any such products that are peptides, Sanofi first develops them for diabetes or obesity in humans and the first application for regulatory approval for such products is for diabetes or obesity in humans in a major country, and for any such products that are not peptides, Sanofi first develops such products for diabetes in humans and animals and the first application for marketing approval is for diabetes in humans in a major country. This license will become exclusive, on a peptide-by-peptide basis, for any licensed product containing a peptide that is non-proprietary to Sanofi and is designated by Sanofi if certain specified conditions are met. Under the agreement, Sanofi has granted us a non-exclusive, royalty-free license (with the right to grant sublicenses) under Sanofi's rights in any improvements generated in connection with the collaboration, to research, develop, make or commercialize products outside the scope of the collaboration and outside the field of diabetes.

In consideration for these licenses to the TransCon technologies and as payment for the assignment of specific diabetes-related product patents, Sanofi provided an aggregate of €25 million in non-refundable, up-front payments to us. Sanofi also committed to fund our development activities for a fixed amount over the first three years of the collaboration, in accordance with an agreed upon development plan. For the first two products developed under the Sanofi collaboration, we are also eligible to receive up to an aggregate of €170 million upon Sanofi's achievement of specified clinical development and regulatory approval milestones and up to an aggregate of €100 million upon Sanofi's achievement of certain sales-related milestones.

The term of the agreement expires upon the expiration of the last to expire of the patents licensed or assigned to Sanofi under the agreement and we currently expect the last-to-expire licensed or assigned patent will expire in October 2030. We may terminate the agreement upon 30 days' prior written notice if Sanofi fails to remit any undisputed sum it must pay to us. Each party may terminate the agreement upon 60 days' prior written notice for the other party's uncured material breach. Sanofi has the right to terminate the agreement in its entirety for convenience upon 90 days' prior written notice. Either party may terminate the agreement by written notice to the other party if the other party institutes a lawsuit or proceeding alleging non-infringement, invalidity or unenforceability with respect to any patent licensed to such other party under the agreement. Upon any such termination by us or by Sanofi for convenience, all licenses granted to Sanofi would terminate and, if such termination is by Sanofi for convenience prior to IND approval of a product under the agreement, we may require Sanofi to assign back to us the assigned patent rights upon payment of a specified amount.

Genentech: TransCon anti-VEGF

Overview and Market Opportunity

TransCon anti-VEGF is a novel compound designed to support up to half-yearly injection of anti-VEGF. Anti-VEGF, also known as anti-vascular endothelial growth factor, therapy currently requires periodic intravitreal injections, or injections into the back of the eye. Lucentis ® is the first anti-VEGF indicated for neovascular wet age-related macular degeneration, macular edema following retinal vein occlusion and diabetic macular edema and has been transformative in the treatment of these diseases. Prior to the introduction of Lucentis ®, most patients experienced progressive and inevitable vision loss. Now patients routinely gain back significant vision and maintain those gains for several years. By working together with Genentech and combining the TransCon technologies with anti-VEGF, we seek to continue to lead innovation in this therapeutic category by significantly reducing the injection frequency and associated patient burden.

There is high interest in developing longer acting therapies for intravitreal drug delivery to reduce the burdensome intravitreal injections required by the current standard of care. In this market, patient compliance remains a challenge and patients and physicians sometimes accept less than optimal dosing frequencies for certain individuals. A reliable and consistent method to achieve visual gains with up to half-yearly dosing represents a potential major breakthrough and could quickly become the new standard of care.

Limitations of Established Long-acting Intravitreal Technologies

Several types of drug-eluting ocular implants are approved in the United States, ranging from biodegradable inserts to non-biodegradable reservoirs. Non-biodegradable implants must be removed after a period of time requiring an additional invasive procedure. Biodegradable systems do not require removal, but are generally associated with erratic drug release and burst release.

Our Solution: TransCon anti-VEGF

Our approach provides a unique opportunity to reduce the frequency of intravitreal injections while enabling the predictable release of an active parent drug from our biodegradable carrier system. We believe our TransCon technologies may enable intravitreal delivery of a variety of molecules, including small molecules, peptides and proteins. Our precise, predictable release of the unmodified drug within the vitreous chamber may maintain therapeutic levels of drug with up to half-yearly administration.

TransCon anti-VEGF is a novel prodrug designed to support up to half-yearly administration frequency, and to provide the same or improved efficacy compared to current intravitreal anti-VEGF injections. Genentech is currently evaluating the safety of various TransCon anti-VEGF prodrug candidates for intravitreal administration.

Strategic Collaboration with Genentech

In July 2013, we entered into a strategic collaboration agreement with Genentech and Roche, referred to collectively as Genentech, under which we granted Genentech an exclusive, worldwide royalty-bearing license to make, use and commercialize products based on the TransCon technologies and any therapeutic or prophylactic compound, other than GLP-1, glucagon and/or insulin, for the treatment and/or prevention of any disease, condition or disorder of the eye, other than diabetic retinopathy. We also granted to Genentech a worldwide, non-exclusive, royalty-bearing license to make, use and commercialize such products to treat diabetic retinopathy. Under the agreement, we are prohibited from conducting, or granting rights to third parties to conduct in connection with any generic version of licensed products, any research, development or commercialization of the licensed intellectual property and technology rights for use in treatment or prevention of any ophthalmic condition or disorder, or for diabetic retinopathy, subject to certain exceptions and conditions. In addition, during the term of the agreement, we are prohibited from developing or commercializing any licensed product that contains a compound that is either proprietary to Genentech and that is the subject of active research and development efforts or subject to payment obligations under the agreement, or for a specified time period, that is one of a group of compounds commercialized and designated by Genentech, in each case for uses other than the treatment or prevention of any ophthalmic condition or disorder, or diabetic retinopathy. Under the agreement, we own any inventions made by either party solely relating to our TransCon technologies under the collaboration. Further, we received a non-exclusive, royalty-free license (with the right to grant sublicenses) under Genentech’s rights in any process invention or joint invention generated in connection with the collaboration, to make, use or sell products (other than glucagon product, GLP-1 product and insulin product) outside the field of treatment and/or prevention of any disease, condition or disorder of the eye.

In consideration for these licenses, Genentech paid us a non-refundable up-front technology license fee of $20 million (~€15 million), and we are eligible to receive milestone payments upon Genentech's achievement of specified development milestones and upon the achievement of the first commercial sale in certain specified markets. For each therapeutic or prophylactic compound containing (i) our TransCon technologies licensed under this agreement and (ii) ranibizumab, the milestone payments shall not exceed $100 million (~€75 million), and for each such compound not containing ranibizumab, the milestone payments under this agreement shall not exceed $80 million (~€60 million). For products commercialized under this agreement, we are also eligible to receive tiered royalties on net sales, subject to customary reductions and offsets. For therapeutic or prophylactic compounds containing ranibizumab, these tiered royalties are at percentages in the mid-single digits but not exceeding the low-teen digits and, for other therapeutic or prophylactic compounds not containing ranibizumab, these tiered royalties are at percentages in the mid-single digit range. Genentech also provides funding for our research and development activities under an agreed-upon plan.

The term of the agreement expires on a product-by-product and country-by-country basis upon expiration of Genentech's obligation to pay us royalties on the net sales of licensed products, which extends until the later of ten years after the first commercial sale of each licensed product in such country, or the expiration of certain patent rights covering such licensed product in such country. Each party may terminate the agreement upon 60 days' prior written notice for the other party's uncured material breach of this Agreement, upon 30 days' prior written notice for the other party's uncured material breach that has a serious adverse effect on the non-breaching party, and upon written notice to the other party upon bankruptcy or insolvency of the other party. Genentech has the right to terminate the agreement in its entirety for convenience upon 90 days' prior written notice, or on a licensed product-by-licensed product basis, by giving 90 days' written notice prior to the first commercial sale of the applicable licensed product and 180 days' written notice thereafter. Genentech may also terminate in the event we undergo a change of control in favor of a competitor of Genentech if that competitor does not segregate our personnel and activities under the agreement. We may terminate the agreement upon written notice to Genentech if Genentech challenges in a court the validity, enforceability or scope of licensed patents, other than to defend itself in a legal proceeding involving such patent rights.

Strategic Investment

VISEN Pharmaceuticals

In November 2018, we announced the formation of VISEN Pharmaceuticals, or Visen, a company established to develop and commercialize our endocrinology rare disease therapies in the People's Republic of China, Hong Kong, Macau, and Taiwan, or Greater China. In connection with the formation of Visen, we granted Visen exclusive rights to develop and commercialize certain product candidates based on our proprietary TransCon technologies, including TransCon hGH, TransCon PTH and TransCon CNP, in Greater China for use in all human indications, subject to certain exceptions. As consideration for the rights granted to Visen, we received 50% ownership in the outstanding shares of Visen and concurrently with the rights we granted to Visen, entities affiliated with Vivo Capital and Sofinnova Ventures purchased shares in Visen for an aggregate purchase price of $40 million in cash.

Market Opportunity in China

China is the second largest pharmaceutical market in the world after the United States and represents one of the fastest growing pharmaceutical markets worldwide. In recent years, the Chinese government has initiated a number of regulatory reforms that are expected to accelerate drug development, as well as drive growth and demand for new therapeutics in China. In addition to joining an international organization that standardizes regulations for clinical development, the National Medical Products Administration (NMPA) has introduced initiatives such as fast track review for drugs for unmet medical needs and adopted new rules that streamline the drug approval process in China for global companies.

We believe Visen supports our strategy to extend our endocrinology rare disease portfolio globally and establish a presence in China in partnership with collaborators who have significant experience and knowledge of the biopharmaceutical opportunity in China. In part because Visen was established in China, we believe Visen will be able to effectively develop and, if approved, market our innovative technologies to address the needs of the local markets in Greater China.

Rights Agreements

Under the Rights Agreements, Visen must use diligent efforts to develop and commercialize licensed products in Greater China. Additionally, we and Visen will conduct certain research and development activities allocated to the respective party under a research and technical development plan, and Visen will reimburse us for costs of conducting such activities, including costs of our personnel committed to performing such activities in Greater China.

We will provide product supply to Visen for use in conducting clinical trials in Greater China pursuant to separate clinical supply agreements entered into concurrently with the Rights Agreements in accordance with the terms and conditions set forth therein. Additionally, we and Visen will negotiate in good faith the terms and conditions governing commercial supply of licensed product to Visen on the terms and conditions set forth in the Rights Agreements.

Under the Rights Agreements, we agreed not to research, develop, or commercialize competing products in Greater China, and Visen agreed not to grant certain rights under its interest in any inventions or intellectual property arising out of the activities conducted under the Rights Agreements to third parties, in each case, under the terms and conditions specified in the Rights Agreements. We will have the right to exploit inventions and intellectual property arising out of the activities conducted under the Rights Agreements outside of Greater China. Additionally, we granted Visen a right of first negotiation to develop and commercialize certain of its endocrinology products in Greater China.

The Rights Agreements continue in effect for as long as a valid claim of a licensed patent exists in Greater China. Visen may terminate a Rights Agreement for convenience, for uncured material breach by us of a Rights Agreement and for our bankruptcy or insolvency-related events. We may terminate a Rights Agreement for certain specified material breaches thereof by Visen, in the event Visen undergoes a change of control in favor of a competitor, if Visen challenges the validity of any of the licensed patents and for Visen's bankruptcy or insolvency-related events.

Shareholders Agreement

In connection with the formation of Visen, on November 7, 2018, we entered into a Shareholders Agreement (the "Shareholders Agreement") providing for certain rights and obligations of Visen and its shareholders. Pursuant to the Shareholders Agreement, Visen and the Visen shareholders agreed to certain negotiated information and inspection rights, rights relating to registration of shares held by shareholders, pro rata rights to participate in future offerings by Visen of certain securities of Visen subject to certain limited exceptions, drag along provisions relating to a change of control of Visen, rights of first refusal and co-sale with respect to proposed sales (if any) by shareholders of Visen (including sales by us).

Pursuant to the Shareholders Agreement, we have the right to designate an individual for election to the board of directors of Visen and Visen has agreed that certain specified events (including a certain liquidation events) shall require the approval of (i) shareholders of Visen holding at least 60% of Visen's Series A preferred shares and/or (ii) certain members of the board of directors. Under the Shareholders Agreement and in connection with the formation of Visen, we have agreed to refrain from carrying out, or engaging in, the research, development, manufacture or commercialization of certain competing products in Greater China.

The Shareholders Agreement terminates by written agreement between us and an entity affiliated with Vivo Capital, and automatically terminates upon the dissolution of Visen. In addition, holders of a specified percentage of Series A preferred shares in Visen can terminate the Shareholders Agreement by written notice to Visen upon the occurrence of certain events set forth in the Shareholders Agreement.

Manufacturing

As we do not maintain the capability to manufacture finished drug products, we utilize contract manufacturers to manufacture finished drug product of our proprietary TransCon product candidates intended for clinical or commercial use. We source starting materials for our manufacturing activities from one or more suppliers. For the starting materials necessary for our proprietary TransCon product candidate development, we have agreements for the supply of such starting materials with drug manufacturers or suppliers that we believe have sufficient capacity to meet our demands. However, from time to time, we source critical raw materials and services from one or a limited number of suppliers and there is a risk that if such supply or services were interrupted, it would materially harm our business. In addition, we typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements. We utilize the services of contract manufacturers to manufacture drug substance required for later phases of clinical development and eventual commercialization for us under all applicable laws and regulations.

We have analytical and process development capabilities in our own facility. We generally perform analytical and process development for our proprietary TransCon product candidates internally and manufacture internally our TransCon product candidates necessary to conduct the non-GLP preclinical studies thereof. However, we occasionally outsource the manufacture of research and development-stage TransCon product candidates. Occasionally our collaboration partners may manufacture the research and development-stage TransCon product candidates for which they are licensed. Each of our collaboration partners have granted us rights that enable us to freely commercialize all improvements to the TransCon prodrug technologies and manufacturing process developed by our collaboration partners outside of the fields of use and/or territories (as applicable) licensed to such collaboration partners under the relevant collaboration agreements with such partners.

We do not have, and we do not currently plan to acquire or develop, the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in human clinical trials. We rely on third-party manufacturers to produce the bulk drug substances required for our clinical trials and expect to continue to rely on third parties to manufacture and test clinical trial drug supplies for the foreseeable future.

Our contract suppliers manufacture drug substance and finished drug product for our TransCon product candidates for clinical trial use in compliance with cGMP and applicable local regulations. cGMP regulations include requirements relating to organization of personnel; buildings and facilities; equipment; control of components and drug product containers and closures; production and process controls; packaging and labeling controls; holding and distribution; laboratory controls; records and reports; and returned or salvaged products. The manufacturing facilities for our products must be in compliance with cGMP requirements, and for device and device components, the Quality System Regulation, or QSR, requirements, before any product is approved. We ensure cGMP compliance of our suppliers through regular quality inspections performed by our Quality Assurance group. Our third-party manufacturers may also be subject to periodic inspections of facilities by the FDA, the Competent Authorities of the Member States of the European Economic Area (EEA, comprising the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein), and other authorities, including reviews of procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. These actions could have a material impact on the availability of our products. In addition, contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

We also contract with additional third parties for the filling, labeling, packaging, testing, storage and distribution of our TransCon product candidates. We employ personnel with the significant scientific, technical, production, quality and project management experience required to oversee our network of third-party suppliers and to manage manufacturing, quality data and information for regulatory compliance purposes.

NOF Manufacturing and Supply Agreement

On December 21, 2017, we entered into a multi-year Manufacturing and Supply Agreement (the “NOF Agreement”) with NOF Corporation (“NOF”). Under the NOF Agreement, NOF has agreed to manufacture and supply the mPEG Linker (the “NOF Product”) for our TransCon hGH product candidate. We have agreed to purchase certain quantities of NOF Product. We may purchase NOF Product from other manufacturers and are not obligated to purchase NOF Product from NOF, other than certain quantities that have been forecasted by us in accordance with a mandatory rolling forecast that we must deliver to NOF from time to time.

The NOF Agreement is effective as of December 21, 2017. The initial term of the NOF Agreement terminates on December 31, 2025 unless earlier terminated. The parties may extend the initial term of NOF Agreement pursuant to a written agreement until five years following the finalization of NOF's capacity expansion. After the expiration of the initial term of the NOF Agreement, the NOF Agreement continues until it is terminated. The NOF Agreement may be terminated (i) by either party for the other party's assignment for the benefit of creditors, insolvency, bankruptcy, liquidation, dissolution, or the taking of any action by the other party under an act for relief from creditors, (ii) by either party for the other party's uncured material breach, (iii) by us after the initial term of the NOF Agreement with one year written notice, or (iv) by mutual agreement of the parties. In addition, the NOF Agreement may be terminated by us in the event of a change of fifty percent or more of the direct or indirect ownership of NOF or manufacturing facilities relevant to the NOF Agreement, if such ownership goes to a third party materially involved in the treatment of growth related disorders in humans. The NOF Agreement may also be terminated by either party for a continuing event of force majeure.

The NOF Agreement contains, among other provisions customary representations and warranties by us and NOF, grants certain limited license rights related to either party's intellectual property in connection with the manufacturing and supply of NOF Product, provides for certain indemnification rights in favor of both parties and customary confidentiality provisions.

Carbogen Manufacturing and Supply Agreement

On October 26, 2018, we entered into a multi-year Manufacturing and Supply Agreement (the "Carbogen Agreement") with Carbogen Amcis AG ("Carbogen"). Under the Carbogen Agreement, Carbogen has agreed to manufacture and supply the C13 Linker (the "Carbogen Product") for our TransCon hGH product candidate. We may purchase C13 Linker from other manufacturers and are not obligated to purchase Carbogen Product from Carbogen, other than certain quantities that have been forecasted by us in accordance with a mandatory rolling forecast that we must deliver to Carbogen from time to time.

The Carbogen Agreement is effective as of October 26, 2018. The initial term of the Carbogen Agreement expires five years after the first commercial launch of our TransCon hGH product candidate (the "Carbogen Initial Term") unless earlier terminated. After the expiration of the Carbogen Initial Term of the Carbogen Agreement, the Carbogen Agreement continues until it is terminated. The Carbogen Agreement may be terminated (i) by either party for the other party's assignment of the Carbogen Agreement for the benefit of creditors, insolvency, bankruptcy, dissolution, or taking of any action under an act for relief from creditors, (ii) by either party for the other party's uncured material breach, (iii) by us after the Carbogen Initial Term of the Carbogen Agreement with one year written notice, (iv) by Carbogen after the Carbogen Initial Term of the Carbogen Agreement with four years written notice (subject to Carbogen's technology transfer obligation to an alternate supplier) or (iv) by mutual agreement of the parties. In addition, the Carbogen Agreement may be terminated by us in the event of a change of fifty percent or more of the direct or indirect ownership of Carbogen, if such ownership goes to a third party materially involved in the treatment of growth-related disorders in humans. The Carbogen Agreement may also be terminated by either party for a continuing event of force majeure.

The Carbogen Agreement contains, among other provisions, certain representations and warranties by us and Carbogen, grants certain rights to intellectual property relating to, or inventions made in connection with, the manufacturing and supply of Carbogen Product, provides for certain indemnification rights in favor of both parties and includes confidentiality provisions.

Philips Medisize (formerly B&O Medicom and Medicom Innovation Partner)

On January 12, 2017, we entered into a multi-year Manufacturing and Supply Agreement (the "Medicom Agreement") with Medicom Innovation Partner ("Medicom"). Under the Medicom Agreement, Medicom has agreed to exclusively manufacture and supply the auto injector injection device (the "Medicom Product") for our TransCon hGH product candidate. We are obligated to purchase certain quantities that have been forecasted by us in accordance with a mandatory rolling forecast that we must deliver to Medicom from time to time.

The Medicom Agreement is effective as of January 12, 2017. The term of the Medicom Agreement terminates on June 30, 2025 ("Initial Term") unless earlier terminated or unless extended unilaterally by us, with notice of extension to be given no later than June 30, 2024, by five years until June 30, 2030 ("Extended Term") after which date it shall continue indefinitely unless terminated. The Medicom Agreement may be terminated (i) by either party for the other party's bankruptcy or insolvency-related events, (ii) by either party for the other party's uncured material breach, (iii) by us by not extending the Initial Term into the Extended Term, (iv) by Medicom after the Extended Term of the Medicom Agreement with two year's advance written notice or by us after the Extended Term of the Medicom Agreement with one year's advance notice, or (v) by Medicom if we purchase less than an agreed volume of the Medicom Product (provided that we may avoid such termination by paying Medicom's lost profits up to such agreed minimum volume). In addition, the Medicom Agreement may be terminated by us in the event of a change of control of Medicom, if such control goes to a third party materially involved in the treatment of certain defined endocrinology disorders in humans. In all events of termination Medicom is obligated to support a tech transfer of manufacture of Medicom Product to an alternate supplier.

The Medicom Agreement contains, among other provisions certain representations and warranties by us and Medicom, grants certain limited license rights related to either party's intellectual property in connection with the manufacturing and supply of Medicom Product, provides for certain indemnification rights in favor of both parties and includes confidentiality provisions.

Vetter Pharma International GmbH

On December 14, 2018, we entered into a multi-year Supply Agreement (the "Vetter Agreement") with Vetter Pharma International ("Vetter"). Under the Vetter Agreement, Vetter has agreed to manufacture and fill-and-finish drug product in dual-chamber cartridges (the "Ascendis Product") for our TransCon hGH product candidate. Vetter has agreed to supply in accordance with a long-term forecast in addition to a rolling forecast with a binding part that we must deliver to Vetter from time to time.

The Vetter Agreement is effective as of January 1, 2019. The term of the Vetter Agreement expires on the five-year anniversary of the date of first regulatory approval of the TransCon hGH product (the "Initial Term") after which term it shall be automatically renewed for subsequent two-year terms unless terminated. The Vetter Agreement may be terminated (i) by either party for the other party's uncured material breach, including certain enumerated events constituting material breach such as bankruptcy or insolvency-related events, (ii) by us with two years' notice, with effect no earlier than two years after expiry of the Initial Term or (iii) by either party if the other party is taken over by our or a Vetter competitor, as applicable.

The Vetter Agreement contains, among other provisions, certain representations and warranties by us and Vetter, grants certain limited license rights in connection with Vetter's manufacturing and supply, and our sale, distribution and other use, of Ascendis Product, provides for certain indemnification rights in favor of both parties and includes confidentiality provisions.

Fujifilm Commercial Supply Agreement

On January 9, 2019, we entered into a multi-year Commercial Supply Agreement (the "Fujifilm Agreement") with Fujifilm Diosynth Biotechnologies UK Ltd. ("Fujifilm"). Under the Fujifilm Agreement, Fujifilm has agreed to manufacture and supply TransCon hGH Drug Substance (the "Fujifilm Product") for our TransCon hGH product candidate. We may purchase TransCon hGH Drug Substance from other manufacturers and are not obligated to purchase Fujifilm Product from Fujifilm, other than a total of 6 batches each year in 2020 and 2021.

The Fujifilm Agreement is effective as of January 9, 2019. The initial term of the Fujifilm Agreement expires on December 31 in the year of the five year anniversary of the first commercial sale of our TransCon hGH product candidate (the "Fujifilm Initial Term") unless earlier terminated. After the expiration of the Fujifilm Initial Term of the Fujifilm Agreement, the Fujifilm Agreement continues until it is terminated. The Fujifilm Agreement may be terminated (i) by either party for the other party's bankruptcy or insolvency-related events, (ii) by either party for the other party's uncured material breach or material breach that is not capable of remedy, (iii) by us after the Fujifilm Initial Term of the Fujifilm Agreement with two years written notice, or (iv) by Fujifilm after the Fujifilm Initial Term of the Fujifilm Agreement with five years written notice. We are entitled to terminate the Fujifilm Agreement

with regards to the manufacture of recombinant hGH after one year following launch with two years written notice. In addition, the Fujifilm Agreement may be terminated by us in the event of a change in control of Fujifilm, where the new controlling entity is our competitor. The Fujifilm Agreement may also be terminated by either party for a continuing event of force majeure.

The Fujifilm Agreement contains, among other provisions, certain warranties by us and Fujifilm, grants certain limited license rights related to either party's intellectual property in connection with the manufacturing and supply of Fujifilm Product, provides for certain indemnification rights in favor of both parties and includes confidentiality provisions.

Competition

The pharmaceutical industry is very competitive and subject to rapid and significant innovation. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies, universities, and other research institutions. Many of our competitors have greater resources, as well as larger research and development functions and more experienced marketing and manufacturing organizations. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are superior to, or more effectively marketed than, the product candidates that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive. For additional information regarding the companies that may be competitive with our product candidates currently in development, please see the descriptions of our current product candidates included above under the caption "TransCon Product Candidates."

In addition, many of our competitors have greater experience than we do in conducting preclinical and clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates more rapidly than we do. Companies that complete clinical trials, obtain required regulatory authority approvals and commence commercial sale of their drugs before their competitors may achieve a significant competitive advantage. Drugs resulting from our research and development efforts or from our joint efforts with collaboration partners therefore may not be commercially competitive with our competitors' existing products or products under development.

We are aware that other companies are developing or evaluating enhanced drug delivery and sustained release technologies, which may be competitive with our TransCon technologies. In particular, we believe Nektar Therapeutics, OPKO Health, Inc., ProLynx LLC and Serina Therapeutics, Inc. are developing technology platforms in the areas of enhanced drug delivery and reversible linkers that may be competitive with our TransCon technologies. We also expect that technological developments will occur at a rapid rate and that competition is likely to intensify as various enhanced delivery and sustained released technologies may achieve similar advantages.

For more information about our revenue and where we compete, please see Note 4 to our audited consolidated financial statements included in Item 18 of this annual report.

Intellectual Property

We actively seek to protect the intellectual property and proprietary technology that we believe is important to our business, which includes seeking and maintaining patents covering our technology, *i.e.*, TransCon linkers and carriers, specific lead candidate structures, broad product concepts, proprietary processes and any other inventions that are commercially and/or strategically important to the development of our business. We also rely on trade secrets that may be important to the development of our business and actively seek to protect the confidentiality of such trade secrets.

Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. For more information, please see "Risk Factors—Risks Related to Our Intellectual Property and Information Technology."

As of December 31, 2018, we own a total of 64 patent families, of which 17 are currently in their priority year or international phase and we own several granted patents in the United States (24), Europe (8), Australia (22), Canada (9), China (7), Israel (9), Korea (2), Malaysia (2), New Zealand (4), Japan (15), Mexico (9), Singapore (5), Russia (5) and South Africa (12) and have approximately 283 pending national/regional applications in a total of 19 jurisdictions (excluding the member states of the European Patent Convention in which our European patents were validated).

So far none of our granted patents has been subject to opposition proceedings, appeals or similar actions aiming at revoking or restricting the scope of a granted patent.

The patent portfolios for the fields containing our most advanced product candidates as of December 31, 2018 are summarized below and the expected expiration dates included in the summary below do not give effect to patent term extensions that may be available.

TransCon hGH

Our patent portfolio related to TransCon hGH includes six patent families relating to different aspects of TransCon hGH and an additional nine patent families covering various aspects of the auto-injector device for administration of TransCon hGH. The first of these patent families is a composition of matter patent family directed to the particular stoichiometry of TransCon hGH and a related TransCon carrier. As of December 31, 2018, this patent family included patents granted in Europe and the United States and a patent application in Europe. We expect any patents granted in this patent family to expire in October 2024.

The second of these patent families is a composition of matter patent family directed to a TransCon linker used in TransCon hGH. As of December 31, 2018, this patent family included patents granted in the United States, Australia, Canada, Japan and Mexico and included patent applications in Europe, the United States, and Brazil. We expect any patents granted in this patent family to expire in March 2025.

The third of these patent families is a composition of matter patent family directed to a broad class of TransCon hGH lead candidate structures. As of December 31, 2018, this patent family included patents granted in the United States, Europe, Australia, Canada, China, Israel, India, Japan, Mexico, Russia and South Africa and included patent applications in Europe, the United States, Brazil, Canada, India, Japan, Mexico and Russia. We expect any patents granted in this patent family to expire in April 2029.

The fourth of these patent families is a composition of matter patent family directed to specific dry pharmaceutical compositions comprising TransCon hGH. As of December 31, 2018, this patent family included patents granted in the United States, Europe, Australia, Israel, Mexico, Singapore and South Africa and included patent applications in the United States, Brazil, Canada, China and India. We expect any patents granted in this patent family to expire in December 2030.

The fifth of these patent families is a composition of matter patent family directed to a broad class of TransCon hGH lead candidate structures. As of December 31, 2018, this patent family included a patent granted in South Africa and patent applications in the United States, Europe, Australia, Brazil, Canada, Israel, Japan, South Korea, Mexico, New Zealand, Russia and Singapore. We expect any patents granted in this patent family to expire in November 2035.

The sixth of these patent families is directed to a particular dosage regimen for long-acting growth hormone formulations. As of December 31, 2018, this patent family included patent applications in the United States and in Europe. We expect any patents granted in this patent family to expire in November 2035.

Two of the nine patent families covering the auto-injector device consist of an international patent application as of December 31, 2018. As of December 31, 2018, each of the other seven patent families included patent applications in the United States, Europe, Australia, Canada, Japan and New Zealand.

TransCon PTH

Our patent portfolio related to TransCon PTH includes six patent families relating to different aspects of TransCon PTH. The first of these patent families is a composition of matter patent family directed to the TransCon linker used in TransCon PTH. As of December 31, 2018, this patent family included granted patents in the United States, Australia, Canada, China, Israel, Japan, Mexico and South Africa and included patent applications in Europe, the United States, the United Arab Emirates, Brazil and Russia. We expect any patents granted in this family to expire in January 2029.

The second of these patent families is a composition of matter patent family directed to a broad class of TransCon PTH candidate structures. As of December 31, 2018, this patent family included patent applications in the United States, Europe, Australia, Brazil, Canada, China, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore, Thailand and South Africa. We expect any patents granted in this patent family to expire in February 2037.

The third and fourth of these patent families are method of treatment patent families directed to a particular dosage regimen. As of December 31, 2018, these patent families consist of an international patent application. We expect any patents granted in this patent family to expire in September 2037.

The fifth of these patent families is a composition of matter family directed to PTH compounds exhibiting a beneficial pharmacokinetic profile. As of December 31, 2018, this patent family consists of an international patent application. We expect any patents granted in this patent family to expire in September 2037.

The sixth patent family relates to a starting dose for treatment with reversible PTH conjugates. As of December 31, 2018, this patent family consists of an EP priority application. We expect any patents granted from this patent family to expire in May 2039.

TransCon CNP

Our patent portfolio related to TransCon CNP includes ten patent families relating to different aspects of TransCon CNP. The first of these patent families is a composition of matter patent family directed to the particular stoichiometry of TransCon CNP and a related TransCon carrier. As of December 31, 2018, this patent family included patents granted in Europe and the United States and a patent application in Europe. We expect any patents granted in this patent family to expire in October 2024.

The second of these patent families is a composition of matter patent family directed to the TransCon linker used in TransCon CNP. As of December 31, 2018, this patent family included granted patents in the United States, Australia, Canada, China, Israel, Japan, Mexico and South Africa and included patent applications in Europe, the United States, the United Arab Emirates, Brazil, Mexico and Russia. We expect any patents granted in this family to expire in January 2029.

The third of these patent families is a composition of matter patent family directed to a broad class of TransCon CNP candidate structures. As of December 31, 2018, this patent family included patent applications in the United States, Europe, Australia, Brazil, Canada, China, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore, Thailand and South Africa. We expect any patents granted in this patent family to expire in January 2036.

The fourth to the ninth patent family are composition of matter patent families directed various CNP compounds having beneficial properties. As of December 31, 2018, the first one of these six patent families included patent applications in the United States, Europe, Australia, Canada, Japan, Mexico, New Zealand and South Africa. As of December 31, 2018, the second one included patent applications in the United States, Europe, Australia, Canada, Japan, New Zealand and South Africa. As of December 31, 2018, the third one included patent applications in the United States, Europe, Australia, Brazil, Canada, China, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Singapore and South Africa. As of December 31, 2018, the fourth one included patent applications in the United States, Europe, Australia, Canada, Israel and New Zealand. As of December 31, 2018, the

fifth one included patent application in the United States, Europe, Australia, Brazil, Canada, China, Israel, South Korea, New Zealand and Singapore. As of December 31, 2018, the sixth one included patent applications in the United States, Europe, Australia, Canada, Israel and New Zealand. We expect any patents granted in this patent family to expire in January 2037.

The tenth patent family covers a combination therapy of TransCon CNP. As of December 31, 2018, this patent family consists of an international patent application. We expect any patents granted from this patent family to expire in September 2037.

Field of Diabetes

In the field of diabetes, our patent portfolio related to TransCon product candidates under development with our collaboration partner, Sanofi, includes four product-specific patent families previously sold to Sanofi and four technology-patent families owned by us and out-licensed to Sanofi. The first patent family owned by us is referred to as our AP006 patent family and this patent family is a composition of matter patent family broadly directed to one of our TransCon linkers. This patent family relates to our TransCon technologies and product candidates in the diabetes and ocular fields, among others. As of December 31, 2018, this patent family included patents granted in the United States, Australia, Canada, China, Israel, Japan, Mexico and South Africa and included patent applications in Europe, the United States, the United Arab Emirates, Brazil, Mexico and Russia. We expect any patents granted in this patent family to expire in January 2029.

The second patent family owned by us is referred to as our AP003 patent family and this patent family is a combination of a composition of matter and a process patent family directed to particular TransCon hydrogels. This patent family relates to our TransCon technologies and product candidates in the diabetes field. As of December 31, 2018, this patent family included three patents granted in the United States and included patent applications in Europe. We expect any patents granted in this patent family to expire in October 2024.

The third patent family is a composition of matter patent family also directed to a PEG-based hydrogel comprising certain backbone and crosslinker structures. As of December 31, 2018, this patent family included patents granted in Australia, Canada, China, Israel, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore and South Africa, and included patent applications in Europe, the United States, Brazil, Indonesia, India and Thailand. We expect any patents granted in this patent family to expire in July 2030.

The fourth patent family owned by us is referred to as our AP019 patent family and this patent family is a process patent family directed to the sterilization of TransCon hydrogels. As of December 31, 2018, this patent family included patents granted in the United States, Europe, Australia, Canada, China, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore and South Africa, and included patent applications in Brazil and Thailand. We expect any patents granted in this patent family to expire in October 2030.

Field of Ophthalmology

Our patent portfolio related to our work in the ophthalmology field includes three patent families, one of which is our AP006 patent family which is described above and two product-related patent families, one of which is exclusively out-licensed to our collaboration partner, Genentech. Other than the AP006 patent family described above, our patent families related to our work in the ocular fields are described in this section below.

The first patent family is a composition of matter patent family directed to the general concept of using hydrogel prodrugs for the treatment of ocular diseases. As of December 31, 2018, this patent family included granted patents in Australia, New Zealand and South Africa and included patent applications in Europe, the United States, Brazil, Canada, Israel, South Korea, Mexico and Malaysia. We expect any patents granted in this patent family to expire in October 2032.

The second patent family, which is exclusively out-licensed to Genentech, is a composition of matter patent family directed to a broad class of TransCon prodrugs of vascular endothelial growth factor neutralizing drugs. As of December 31, 2018, this patent family included granted patents in Australia, New Zealand, Russia, Singapore and South Africa and included patent applications in Europe, the United States, Brazil, Canada, Israel, Japan, South Korea, Mexico and Malaysia. We expect any patents granted in this patent family to expire in October 2033.

TransCon Technologies

Our patent portfolio also includes patents and patent applications generally relating to our TransCon technologies, including TransCon linkers, TransCon carriers and certain soluble conjugates. We own an aggregate of ten patent families relating to TransCon linkers, the material components of which are described above. We own an aggregate of nine patent families relating to TransCon carriers, the material components of which are described above. Finally, we own a composition of matter patent family that is directed to soluble conjugates in which one drug molecule is connected to one TransCon carrier molecule. As of December 31, 2018, this patent family included patents in Europe and the United States and patent applications in Europe. We expect any patents granted in this patent family to expire in October 2024.

Laws and Regulations Regarding Patent Terms

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent term may be shortened if a patent is terminally disclaimed over another patent or if there are delays in patent prosecution by the patentee. A patent's term may be lengthened by a patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent. The patent term of a European patent is 20 years from its filing date, which, unlike in the United States, is not subject to patent term adjustments.

The term of a patent that covers an FDA-approved drug or biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug or biologic is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We anticipate that some of our issued patents may be eligible for patent term extensions.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, safety surveillance, efficacy, quality control, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, sale, import, export and the reporting of safety and other post-market information of pharmaceutical and medical device products such as those we are developing. A new drug must be approved by the FDA through the NDA process and a new biologic must be licensed by the FDA through the BLA process before it may be legally marketed in the United States. Similarly, new drugs and biologics must be approved by the EMA through the marketing authorization application, or MAA, process before they may be legally marketed in Europe. Our product candidates will be subject to similar requirements in other countries prior to marketing in those countries. The processes for obtaining regulatory approvals in the United States, the EEA and in foreign countries, along with subsequent compliance with appropriate federal, state, local and foreign statutes and regulations, require the expenditure of substantial time and resources.

U.S. Government Regulation

In the United States, we are subject to extensive regulation by the FDA, which regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and in the case of biologics, also under the Public Health Service Act, or PHSA, and their implementing regulations, and other federal, state, and local regulatory authorities. The FDCA, PHSA and their implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs or BLAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug or biological product for each indication;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's or biologic's identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

We are developing an auto-injector with Medicom Innovation Partner A/S to facilitate the administration of TransCon hGH by end-users. Typically, the FDA's Office of Combination Products assigns a combination product to a specific Agency Center as the lead reviewer after an applicant submits a Request for a Designation. The FDA determines which Center will lead a product's review based upon the product's primary mode of action. Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application. However, the FDA sometimes will require separate marketing applications for individual constituent parts of the combination product which may require additional time, effort, and information. Even when a single marketing application is required for a combination product, such as an NDA for a combination pharmaceutical and device product, both the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health will participate in the review. An applicant will also need to discuss with the Agency how to apply certain premarket requirements and post-marketing regulatory requirements, including conduct of clinical trials, adverse event reporting and good manufacturing practices, to their combination product.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND is a request for authorization from the FDA to administer an investigational pharmaceutical product to humans. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other

things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective and a clinical trial proposed in the IND may begin 30 days after the FDA receives the IND, unless during this 30-day waiting period, the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical Trials

Clinical trials involve the administration of the investigational pharmaceutical product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their www.clinicaltrials.gov website.

Human clinical trials are typically conducted in three or four sequential phases, which may overlap or be combined:

- phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- phase 2: The product candidate is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- phase 3: The product candidate is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.
- phase 4: In some cases, the FDA may conditionally approve an NDA or BLA for a product candidate on the sponsor’s agreement to conduct additional clinical trials after NDA or BLA approval. In other cases, a sponsor may voluntarily conduct additional clinical trials post approval to gain more information about the drug or biologic. Such post approval trials are typically referred to as phase 4 clinical trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, phase 2 and phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the product candidate has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

During the development of a new drug or biologic, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug or biologic. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar pharmaceutical products, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval or licensure to market the product for one or more indications. In most cases, the submission of an NDA or BLA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act guidelines that are currently in effect, the FDA has a goal of 10 months from the date of "filing" of a standard NDA for a new molecular entity or original BLA to review and act on the submission. This review typically takes 12 months from the date the NDA or BLA is submitted to the FDA because the FDA has sixty days to decide whether an application is accepted for filing, as described below.

In addition, under the Pediatric Research Equity Act of 2003 as amended and reauthorized, certain NDAs or BLAs or supplements to an NDA or BLA must contain data that are adequate to assess the safety and effectiveness of the drug or biologic for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs and BLAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency.

The FDA may refer an application for a novel drug or biologic to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

The FDA generally accepts data from foreign clinical trials in support of an NDA or BLA if the trials were conducted under an IND. If a foreign clinical trial is not conducted under an IND, the FDA nevertheless may accept the data in support of an NDA or BLA if the study was conducted in accordance with GCP requirements and the FDA is able to validate the data through an on-site inspection, if deemed necessary. Although the FDA generally requests that marketing applications be supported by some data from domestic clinical studies, the FDA may accept foreign data as the sole basis for marketing approval if (1) the foreign data are applicable to the U.S. population and U.S. medical practice, (2) the studies were performed by clinical investigators with recognized competence, and (3) the data may be considered valid without the need for an on-site inspection or, if the FDA considers the inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

The testing and approval process for an NDA or BLA requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all.

After evaluating the NDA or BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA or BLA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs and biologics manufactured or distributed pursuant to FDA approvals and licenses are subject to pervasive and continuing regulation by the FDA and other government authorities, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval.

There also are continuing, annual program fee requirements for any marketed products.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug and biologics manufacturers and other entities involved in the manufacture and distribution of approved drugs and biologics are required to register their establishments with the FDA and state authorities and are subject to periodic unannounced inspections by the FDA and these state authorities for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program.

Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or BLAs or supplements to approved NDAs or BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease

or condition will be recovered from sales of the product in the United States. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, by providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication that could be used "off label" by physicians in the orphan indication, even though the competitor's product is not approved in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do of the same product, as defined by the FDA, for the same indication we are seeking, or if our product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity.

Pediatric Exclusivity

Pediatric exclusivity is a type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the five-year and three-year non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA or BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical study is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of FDA-requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application relying on the NDA or BLA sponsor's data.

Biosimilars and Exclusivity

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, few biosimilars have been licensed under the BPCIA, although numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being addressed by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own

preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the twelve-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty.

Foreign Regulation

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. For example, in the European Union, we must obtain authorization of a clinical trial application, or CTA, in each member state in which we intend to conduct a clinical trial. Even if we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

To obtain a marketing authorization of a drug in the European Union, we may submit MAAs either under the so-called centralized or national authorization procedures.

Centralized Procedure

The centralized procedure provides for the grant of a single marketing authorization from the European Commission following a favorable opinion by the Committee for Medicinal Products for Human Use, or the CHMP, of the EMA that is valid in all European Union member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products) and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding clock stops.

National Authorization Procedures

There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.

- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

The EEA has a procedure, the so-called hybrid marketing authorization application process, for the approval of products that are similar to an already approved product (the reference product), but that do not qualify as generics. The legal basis for this process is established in Article 10(3) of Directive 2001/83/EC which provides that the hybrid application process is available for products that are similar to an already authorized product, but do not fall within the definition of a generic medicinal product, their bioequivalence to the reference product cannot be demonstrated through bioavailability studies, or their active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration differ from that of the reference product. Marketing authorization applications for hybrid products can rely in part on the results of the preclinical tests and clinical trials of the reference product and in part on new data. A hybrid of a reference medicinal product authorized via the centralized procedure has automatic access to the centralized procedure.

In the European Union, new products authorized for marketing (*i.e.*, reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the European Union during a period of eight years from the date on which the reference product was first authorized in the European Union. The market exclusivity period prevents a successful generic applicant from commercializing its product in the European Union until 10 years have elapsed from the initial authorization of the reference product in the European Union. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

In the EEA, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the E.U. Community and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the medicinal product. An E.U. orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or the PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the European Union and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension. For orphan-designated medicinal products, the 10-year period of market exclusivity is extended to 12 years.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, other U.S. federal and state healthcare regulatory laws restrict business practices in the biopharmaceutical industry, which include, but are not limited to, state and federal anti-kickback, false claims, data privacy and security, and physician payment and drug pricing transparency laws.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not meet the requirements of a statutory or regulatory exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The majority of states also have anti-kickback laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The federal civil False Claims Act prohibits any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-covered, uses. In addition, the civil monetary penalties statute imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Many states also have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act broadened the reach of certain criminal healthcare fraud statutes created under HIPAA by amending the intent requirement such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act imposed, among other things, new annual reporting requirements for covered manufacturers for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $169,170 per year and up to an aggregate of $1,127,799 per year for "knowing failures." Covered manufacturers must submit reports by the 90th day of each subsequent calendar year. In addition, certain states require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices, and/or tracking and reporting of marketing expenditures and pricing information as well as gifts, compensation and other remuneration or items of value provided to physicians and other healthcare professionals and entities.

Privacy and data security have become significant issues in the United States, Europe and in many other jurisdictions where we may in the future conduct our operations. As we receive, collect, process, use and store personal and confidential data, we are subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA, and, in the European Union, the General Data Protection Regulation, or GDPR.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

On May 25, 2018, the GDPR entered into force and became directly applicable in all EU member states. The GDPR implements more stringent operational requirements than its predecessor legislation. For example, the GDPR requires more detailed disclosures to data subjects, requires disclosure of the legal basis for processing personal data, makes it harder obtain valid consent for processing, will require the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the EU, imposes additional obligations when contracting with service providers and requires us to adopt appropriate privacy governance including policies, procedures, training and data audit. Noncompliance with the GDPR can result in fines of up to the greater of €20 million or up to 4% of total global annual revenue in the event of a significant breach.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug or medical device products for which we obtain regulatory approval. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of any products for which we receive regulatory approval for commercial sale will therefore depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations.

The process for determining whether a third-party payor will provide coverage for a drug or medical device product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a third-party payor's decision to provide coverage for a drug or medical device product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for new products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drugs, medical devices and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the Affordable Care Act was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans, imposed mandatory discounts for certain Medicare Part D beneficiaries, subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs and imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices, which was subsequently suspended until January 1, 2020.

We expect that the current presidential administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. For example, the Tax Cuts and Jobs Act was enacted, which, among other things, removes penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and

therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Trump Administration and the Centers for Medicare & Medicaid Services have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA. There may be additional challenges and amendments to the ACA in the future.

On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. These measures include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Similar political, economic and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system and international healthcare systems. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

C. Organizational Structure

Certain of our operations are conducted through our following wholly-owned subsidiaries: Ascendis Pharma GmbH (Germany), Ascendis Pharma, Inc. (Delaware, United States), Ascendis Pharma, Ophthalmology Division A/S (Denmark), Ascendis Pharma, Endocrinology Division A/S (Denmark), Ascendis Pharma Bone Diseases A/S (Denmark) and Ascendis Pharma Growth Disorders A/S (Denmark). These subsidiaries are also set forth in Exhibit 8.1 to this annual report.

D. Property, Plant and Equipment

Our headquarters are located at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark, where we lease approximately 5,478 square meters of office space. The lease commenced on on July 1, 2018 and can be terminated at the earliest on July 1, 2024 for 1,223 square meters and on July 1, 2026 for 4,255 square meters. In addition, we have expanded the lease with 1,861 square meters of office space, commencing on January 1, 2019 and expiring on July 1, 2026. Our leases at Tuborg Boulevard 12 can be extended until July 1, 2029.

Further, we have entered into an additional lease of approximately 1,397 square meters of office space at Tuborg Boulevard 5, DK-2900 Hellerup, Denmark which commenced on December 1, 2015 and can be terminated at the earliest on November 30, 2022. In addition, we have entered into a lease of additional 170 square meters of office space at Tuborg Boulevard 5. This lease commenced on April 1, 2017 and can be terminated at the earliest on November 30, 2022. Our leases at Tuborg Boulevard 5 can be extended until November 30, 2028.

We maintain a research facility in Heidelberg, Germany, where we lease approximately 2,134 square meters of office and laboratory space. The lease for our Heidelberg facility is continuously extended for 24 months periods. The current extension period expires on January 31, 2021.

In Palo Alto, California, we have leased 465 square meters of office space pursuant to a lease that expires on March 15, 2021, which may be extended for three years at our option, subject to certain conditions. In addition, we have entered into a lease of 1,134 square meters of office space, that commenced on May 1, 2018 and expires on April 30, 2022.

We believe that our existing facilities, including the new leases to commence in 2019, are adequate for our near-term needs. We believe that suitable additional or alternative space would be available if required in the future on commercially reasonable terms.

Item 4A *Unresolved Staff Comments*

Not applicable.

Item 5 *Operating and Financial Review and Prospects*

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the “Selected Financial Data” section of this annual report and our consolidated financial statements and related notes appearing elsewhere in this annual report. In addition to historical information, this discussion contains forward-looking statements based on our current expectations that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the “Risk Factors” and “Forward-Looking Statements” sections and elsewhere in this annual report.

A. Operating Results

Overview

We are applying our innovative TransCon technologies to build a leading, fully integrated biopharmaceutical company and to develop a pipeline of product candidates with potential best-in-class profiles to address unmet medical needs. We have created a portfolio of potential best-in-class rare disease endocrinology product candidates to address unmet medical needs by utilizing our TransCon technology with clinically validated parent drugs. We currently have three product candidates in clinical development in rare endocrine diseases and we are working to apply our technologies in additional therapeutic areas, including oncology. Additionally, we have developed a pipeline of sustained release prodrug product candidates through strategic collaborations and we are working with these collaboration partners in the areas of ophthalmology and diabetes.

Our most advanced product candidate, TransCon hGH, is in development as a once-weekly long acting prodrug of recombinant human growth hormone, also referred to as hGH, as a potential treatment for growth hormone deficiency, or GHD. In January 2018, we completed enrollment in the pivotal phase 3 trial of TransCon hGH, the heiGHt Trial, in pediatric subjects with GHD. On March 4, 2019, we announced top-line results from the heiGHt Trial. We are also conducting two additional trials with TransCon hGH, the fliGHt Trial, which evaluates TransCon hGH in pediatric subjects previously treated with daily hGH, and the enliGHten Trial, which evaluates long-term safety of TransCon hGH in subjects from both the heiGHt and fliGHt Trials. In September 2018, we completed

enrollment in the fliGHt Trial, an open-label trial evaluating TransCon hGH in pediatric subjects with GHD who switched from daily hGH therapy. As a result, more than 300 subjects have now enrolled in the phase 3 TransCon hGH program, which includes the heiGHt, fliGHt and enliGHten Trials. We believe that TransCon hGH may offer a once-weekly therapy for GHD with the potential to improve outcomes compared to currently approved daily hGH. We expect a clinical database lock for the TransCon hGH phase 3 program in pediatric GHD during the third quarter of 2019. Subsequently, we intend to submit a Biologics License Application, or BLA, to the U.S. Food and Drug Administration, or the FDA, for TransCon hGH to treat pediatric GHD in the first half of 2020. We have also conducted a phase 2 clinical trial in adult subjects with GHD that will form the basis of designing future clinical research in adult GHD. If approved, TransCon hGH may reduce the burden of daily treatment by requiring significantly fewer injections, which may improve compliance and treatment outcomes.

We are also using our TransCon technology platform to develop TransCon PTH, a once-daily long-acting prodrug of parathyroid hormone, or PTH, as a potential treatment for hypoparathyroidism, a rare endocrine disorder of calcium and phosphate metabolism. We completed a phase 1 trial in healthy subjects in May 2018, the results of which were consistent with our target product profile for TransCon PTH as a true replacement therapy. In this trial, TransCon PTH showed the predicted pharmacokinetic and pharmacodynamic response, suggesting the ability to normalize serum and urinary calcium levels in patients with hypoparathyroidism. We believe TransCon PTH may provide patients suffering from hypoparathyroidism with a PTH replacement therapy that is designed to fully address all aspects of the disease more than standard of care or currently approved therapies. In June 2018, we were granted Orphan Drug Designation, or ODD, by the FDA for TransCon PTH. ODD is provided to drugs that are intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. We initiated the phase 2 trial in adult subjects with hypoparathyroidism in the first quarter of 2019 with the goal of evaluating different fixed doses of TransCon PTH and a titration regimen for complete withdrawal of standard of care (i.e., calcium and active Vitamin D supplementation), using a ready-to-use prefilled pen device. Our plan for our phase 3 program for TransCon PTH includes incorporating trial sites in the United States, Europe, Australia, Canada, Japan and possibly other Asian countries.

We are also developing TransCon CNP, a long-acting prodrug of C-type natriuretic peptide, as a potential therapeutic option for achondroplasia, the most common form of dwarfism. Currently, there are no medical therapies for achondroplasia approved by the FDA. TransCon CNP utilizes our TransCon technology platform to create a long-acting C-type natriuretic peptide, or CNP, prodrug as a potential therapeutic option for achondroplasia and potentially other skeletal disorders. CNP as a therapeutic approach is supported by extensive preclinical and clinical data. In November 2018, we reported preliminary results from a phase 1 clinical trial in healthy adult subjects, which supported our target product profile for TransCon CNP. In February 2019, we were granted ODD by the FDA for TransCon CNP. Our goal is to develop TransCon CNP as a safe and effective therapeutic option for achondroplasia and potentially other related growth disorders.

In addition to our pipeline of candidates in rare endocrine disorders, in January 2019, we announced that we are establishing oncology as our second independent therapeutic area of focus for our TransCon technology platforms. Our goal is to improve treatment efficacy while limiting or reducing toxicity by applying TransCon technologies to clinically validated drugs, using our unique algorithm for product innovation. We are conducting preclinical studies within the field of oncology to explore multiple potential product candidates and evaluate systemic as well as localized delivery systems using our TransCon platform.

In November 2018, we announced the formation of VISEN Pharmaceuticals, or Visen, a company established to develop and commercialize our endocrinology rare disease therapies in the People’s Republic of China, Hong Kong, Macau and Taiwan, or Greater China. In connection with the formation of Visen, we granted Visen exclusive rights to develop and commercialize certain product candidates based on our proprietary TransCon technologies, including TransCon hGH, TransCon PTH and TransCon CNP, in Greater China for use in all human indications, subject to certain exceptions. As consideration for the rights granted to Visen, we received 50% ownership in the outstanding shares of Visen and concurrently with the rights we granted to Visen, entities affiliated with Vivo Capital and Sofinnova Ventures purchased shares in Visen for an aggregate purchase price of $40 million in cash. We believe Visen supports our strategy to extend our endocrinology rare disease portfolio globally and establish a presence in China in partnership with collaborators who have significant experience and knowledge of the biopharmaceutical opportunity in China. In part because Visen was established in China, we believe Visen will be able to effectively develop and, if approved, market our innovative technologies to address the needs of the local markets in Greater China.

In addition, we have strategic collaborations for TransCon anti-VEGF in the field of ophthalmology, which is partnered with Genentech, and the TransCon peptide program for the treatment of diabetes, which is partnered with Sanofi. We are eligible to receive up to an aggregate of €200 million in development and regulatory milestone payments for products currently being developed under our collaboration agreements, as well as sales-based milestone payments and royalties on future net sales of products.

We believe that the effectiveness of our TransCon technology platforms is supported by data from our preclinical research and the ongoing clinical programs, including our TransCon hGH, TransCon PTH and TransCon CNP programs, as well as findings from our ongoing development of other product candidates, including our multi-product collaborations with Sanofi and Genentech. We have applied TransCon technologies in combination with parent drugs with clinical proof of concept using our algorithm for creating products with the potential to be best-in-class in endocrinology rare diseases, and we will continue to apply this algorithm for product selection in new therapeutic areas. We believe this approach may reduce the risks associated with traditional drug development.

We commenced operations in December 2007 in connection with the acquisition of the company that invented our TransCon technologies, Complex Biosystems GmbH. Since we commenced operations in 2007, we have devoted substantially all of our efforts to developing our product candidates, including conducting preclinical studies and clinical trials and providing general and administrative support for these operations. We do not have any approved products and have never generated any revenue from product sales.

We had a net loss of €130.1 million for the year ended December 31, 2018 compared to a net loss of €123.9 million for the year ended December 31, 2017, and a net loss of €68.5 million for the year ended December 31, 2016. Our total equity was €280.1 million as of December 31, 2018 compared to €187.2 million as of December 31, 2017. We have not generated royalties or revenues from product sales, and do not expect to generate royalties or revenues from product sales prior to regulatory approval of any of our product candidates.

We believe that at some point in the future we will need substantial additional capital to support our operating activities and adequate funding may not be available to us on acceptable terms, or at all.

We anticipate that our expenses will increase substantially in the future as we:

- pursue clinical development, and commercialization of TransCon hGH for the treatment of pediatric GHD and other potential indications;
- pursue clinical development of TransCon PTH for the treatment of hypoparathyroidism and clinical development of TransCon CNP for the treatment of achondroplasia and other FGFR-related rare diseases;
- identify and progress development of new product candidates including in oncology and other new therapeutic areas;
- continue to invest in our TransCon technologies, including our intellectual property, our lab, clinical and commercial scale manufacturing capabilities and our methods and know-how;
- hire additional personnel, particularly in our research and development, clinical supply and quality control groups;
- add operational, financial and management information systems and related finance and compliance personnel; and
- continue to operate as a public company.

Collaboration Agreements

Sanofi

In December 2010, we entered into a strategic collaboration agreement with Sanofi under which we assigned to Sanofi certain diabetes-related patent rights, and granted to Sanofi an exclusive, worldwide, royalty-free license to research, develop, make and commercialize (1) products based on the TransCon technologies and any combination of glucagon-like-peptide-1, or GLP-1, glucagon and insulin to treat any diseases in humans or animals, or (2) any other product developed by Sanofi incorporating our TransCon technologies, other technology covered by the assigned patents or other improvements to our TransCon technologies or the foregoing products, to treat diabetes in humans or animals.

In consideration for these licenses to the TransCon technologies and as payment for the assignment of specific diabetes-related product patents, Sanofi provided an aggregate of €25 million in non-refundable, up-front payments to us. Sanofi also committed to fund our development activities for a fixed amount over the first three years of the collaboration, in accordance with an agreed upon development plan. For the first two products developed under the Sanofi collaboration, we are also eligible to receive up to an aggregate of €170 million upon Sanofi's achievement of specified clinical development and regulatory approval milestones and up to an aggregate of €100 million upon Sanofi's achievement of certain sales-related milestones.

Genentech

In July 2013, we entered into a strategic collaboration agreement with Genentech, under which we granted Genentech an exclusive, worldwide royalty-bearing license to make, use and commercialize products based on the TransCon technologies and any therapeutic or prophylactic compound, other than GLP-1, glucagon and/or insulin, for the treatment and/or prevention of any disease, condition or disorder of the eye, other than diabetic retinopathy. We also granted to Genentech a worldwide, non-exclusive, royalty-bearing license to make, use and commercialize such products to treat diabetic retinopathy.

In consideration for these licenses, Genentech paid us a non-refundable up-front technology license fee of $20.0 million (~€15.0 million), and we are eligible to receive milestone payments upon Genentech's achievement of specified development milestones and upon the achievement of the first commercial sale in certain specified markets. For each therapeutic or prophylactic compound containing (i) our TransCon technologies licensed under this agreement and (ii) ranibizumab, the milestone payments shall not exceed $100 million (~€75 million), and for each such compound not containing ranibizumab, the milestone payments under this agreement shall not exceed $80 million (~€60 million). For products commercialized under this agreement, we are also eligible to receive tiered royalties on net sales, subject to customary reductions and offsets. For therapeutic or prophylactic compounds containing ranibizumab, these tiered royalties are at percentages in the mid-single digits but not exceeding the low-teen digits and, for other of therapeutic or prophylactic compounds not containing ranibizumab, these tiered royalties are at percentages in the mid-single digit range. Genentech also provides funding for our research and development activities under an agreed-upon plan.

Financial Operations Overview

Revenue

To date, we have only generated revenue from license fees, the assignment of certain intellectual property rights, research and development services rendered under collaboration agreements and feasibility studies performed for potential partners. We have not yet generated any revenue from commercial product sales. Our collaboration agreements comprise elements of up-front license fees, milestone payments based on development and sales and royalties based on product sales. In addition, our collaboration agreements contemplate our involvement in the ongoing research and development of our partnered product candidates, for which we are paid fees for the services we render.

In addition to the revenue that we have generated from our collaborations, we may also generate revenue for services performed on feasibility studies for potential partners to evaluate if our TransCon technologies enable certain advantages for their product candidates of interest. Such feasibility studies may be structured as short-term agreements with fixed fees for the work that we perform.

The timing of our operating cash flows may vary significantly from the recognition of the related revenue. In general, income from up-front or initiation payments is deferred and recognized as revenue over the period of continued involvement. Other revenue, such as milestone payments or service fees, is recognized when earned; that is, when the milestone has been achieved or the services have been performed. Our revenue has varied substantially, and is expected to continue to vary, from quarter-to-quarter and year-to-year, depending upon, among other things, the structure and timing of milestone events, the number of milestones achieved, the level of revenues earned for ongoing development efforts, any new collaboration arrangements we may enter into and the terms we are able to negotiate with our collaboration partners. We therefore believe that period-to-period comparisons should not be relied upon as indicative of our future revenues.

Research and Development Costs

Research and development costs represent costs incurred to conduct discovery and development of our proprietary product candidates. We expense all research costs as they are incurred, with development costs being expensed to the extent they do not meet the criteria for capitalization. To date, we have not capitalized any of our development costs.

Our research and development costs consist primarily of manufacturing costs, preclinical and clinical study costs, personnel costs, the cost of facilities, the cost of obtaining and maintaining our intellectual property portfolio, and the depreciation of assets used in research and development activities. Personnel costs consist of salaries, benefits and share-based payment.

Government grants are recognized when there is reasonable assurance that the conditions underlying the grant have been met and that the grant will be received. We did not receive any government grants in 2018, 2017 or 2016. Government grants to cover research and development costs incurred are recognized as a reduction of research and development costs proportionally over the periods during which the related research and development expenses are incurred.

We manage our research and development costs on a consolidated portfolio basis, and do not track or manage total research and development costs by product candidate or by development project. Our research and development costs comprise both direct costs and indirect costs. Direct costs comprise external costs and/or costs that are individually allocable to particular development projects, such as manufacturing costs, preclinical and clinical study costs and certain consultancy fees to the extent such fees are tracked on a product candidate-by-product candidate basis. External costs are tracked on a product candidate-by-product candidate basis only once a product has reached a more advanced stage of development. Indirect costs comprise internal costs and costs that are not attributable to a particular development project or product candidate or that apply to the research and development organization in general.

For the year ended December 31, 2018, we incurred direct and indirect research and development costs of €89.5 million and €50.8 million, respectively, compared to €67.0 million and €32.6 million, respectively, for the year ended December 31, 2017 and €41.6 million and €24.4 million, respectively, for the year ended December 31, 2016.

The division between direct and indirect research and development costs is not necessarily indicative of how we allocate resources to specific projects or the overall use of resources within our research and development organization. Certain research and development costs related to our partnered product candidates are incurred by or reimbursed by our collaboration partners, which has the effect of reducing or eliminating the research and development costs incurred by us for such product candidates. Furthermore, our collaboration partners typically carry the majority of the research and development costs for product candidates at amounts that are not known or made available to us. Therefore, our research and development costs will not reflect a complete picture of all financial resources devoted to our product candidates, nor will such historical costs necessarily reflect the stage of development for particular product candidates or development projects.

We expect our research and development costs to increase in the future as we continue development of our product candidates and advance our discovery and research projects into preclinical development.

The successful development of our product candidates is highly uncertain. At this time we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- clinical trial and early-stage results;
- the terms and timing of regulatory approvals;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the ability to market, commercialize and achieve market acceptance for our product candidates.

A change in the outcome of any of these variables with respect to the development of our product candidates could mean a significant change in the costs and timing associated with the development of such product candidate. For example, if the FDA or other regulatory authority were to require us to conduct preclinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of the clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, facility costs, and other expenses for professional services, including legal, human resource, commercial, audit, tax and accounting services, and the depreciation of assets used in administrative activities. Personnel costs consist of salaries, benefits and share-based payment.

We expect our general and administrative expenses to increase in the future as we expand our operating activities and prepare for potential commercialization of our product candidates, increase our headcount, and support our operations as a public company, including increased expenses related to commercial activities, legal, accounting, regulatory and tax-related services associated with maintaining compliance with the rules and regulations applicable to companies listed on a securities exchange, and costs related to compliance and reporting obligations pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC. In addition, we expect to incur increased expenses related to additional insurance, investor relations activities and other increases related to needs for additional administration and professional services associated with being a public company.

Finance Income and Finance Expenses

We do not hold any interest-bearing debt. As such, finance income and finance expenses consist primarily of interest income, realized and unrealized exchange rate gains and losses on cash, receivables and payables in foreign currencies. As we undertake transactions denominated in foreign currencies, we are exposed to exchange rate fluctuations. We manage our exchange rate exposure through maintaining positions in the various currencies used in the operations and managing payments from the most appropriate positions. We are primarily exposed to movements in U.S. Dollars, or USD, British Pounds, or GBP, and Danish Kroner, or DKK. We do not enter into derivative financial instruments to manage our exposure to exchange rate risks

Results of Operations

Comparison of the years ended December 31, 2018, 2017 and 2016:

	Year Ended December 31,		
	2018 (EUR'000)	2017 (EUR'000)	2016 (EUR'000)
Revenue	10,581	1,530	4,606
Research and development costs	(140,281)	(99,589)	(66,022)
General and administrative expenses	(25,057)	(13,482)	(11,504)
Operating profit / (loss)	**(154,757)**	**(111,541)**	**(72,920)**
Share of profit / (loss) in associate	(321)	—	—
Finance income	24,714	923	7,300
Finance expenses	(127)	(13,756)	(3,112)
Profit / (loss) before tax	**(130,491)**	**(124,374)**	**(68,732)**
Tax on profit / (loss) for the year	394	477	227
Net profit / (loss) for the year	**(130,097)**	**(123,897)**	**(68,505)**

Revenue

The following table summarizes our revenue for the years ended December 31, 2018, 2017 and 2016:

	Year Ended December 31,		
	2018 (EUR'000)	2017 (EUR'000)	2016 (EUR'000)
Revenue from the rendering of services	1,215	1,530	1,628
"Right-to-access" license income	—	—	2,978
"Right-to-use" license income	9,366	—	—
Total revenue	**10,581**	**1,530**	**4,606**

Revenue for the year ended December 31, 2018 was €10.6 million, an increase of €9.1 million, or 592%, compared to €1.5 million for the year ended December 31, 2017. The change was due to recognition of revenue from sale of "right-to-use" licenses to VISEN Pharmaceuticals of €9.4 million, partly offset by a decrease of €0.3 million in revenue from rendering of services, primarily due to fewer services rendered by us under our collaboration with Genentech.

Revenue for the year ended December 31, 2017 was €1.5 million, a decrease of €3.1 million, or 67%, compared to €4.6 million for the year ended December 31, 2016. This change was due to a decrease of €3.0 million in license income, as the recognition of deferred income under our initial collaboration with Genentech had been completed by the end of 2016, and a decrease of €0.1 million in revenue from rendering of services under the same collaboration, due to fewer services rendered by us.

As of December 31, 2018, we had deferred income of €6.9 million under the agreement with VISEN Pharmaceuticals, compared to deferred income from other collaboration agreements of €0 million and €0.1 million as of December 31, 2017 and 2016, respectively. This deferred income is recognized as revenue as we and our collaboration partners advance the projects that are subject to our collaborations.

Research and Development Costs

Research and development costs were €140.3 million for the year ended December 31, 2018, an increase of €40.7 million, or 41% compared to €99.6 million for the year ended December 31, 2017. The change was primarily attributable to a €11.8 million increase in external development costs related to our TransCon hGH product candidate, including costs for preparation of validation batches, or process performance qualification batches, development of the auto-injector to facilitate the administration of TransCon hGH by patients, and increasing costs of the ongoing clinical trials for this product candidate. External development costs to our TransCon PTH project increased by €6.5 million, reflecting the continued development and progress with this product candidate, including manufacturing of clinical material and pen device, and preparation for initiation of a phase 2 study in the first quarter of 2019. External development costs to our TransCon CNP project increased by €3.9 million, reflecting increasing clinical study costs and manufacturing of clinical material. We completed a phase 1 study with TransCon CNP in November 2018, and we are preparing for a phase 2 study to be initiated in the third quarter of 2019.

Other research and development costs increased by €18.5 million, primarily driven by an increase in personnel costs of €6.7 million and non-cash share-based payment of €5.4 million due to a higher number of employees in research and development functions, but also reflecting increases of €1.9 million in facility costs and €1.0 million in IT costs allocated to research and development functions. Professional fees including recruitment costs increased by €1.5 million, and other costs, including travel, conferences and laboratory operations increased by a total of €2.0 million. Research and development costs included non-cash share-based payment of €10.2 million for the year ended December 31, 2018, compared to €4.8 million for the year ended December 31, 2017.

Research and development costs were €99.6 million for the year ended December 31, 2017, an increase of €33.6 million, or 51%, compared to €66.0 million for the year ended December 31, 2016. This change was primarily attributable to a €12.5 million increase in external development costs related to our ongoing pivotal global phase 3 heiGHt study of TransCon hGH and related manufacturing costs for this product candidate, including development of the auto-injector to facilitate the administration of TransCon hGH by patients. External development costs to TransCon PTH and TransCon CNP increased by €7.4 million and €5.2 million, respectively, reflecting the continued development and progress with these two product candidates, including initiation of a phase 1 study with TransCon PTH in September 2017. Other research and development costs increased by €8.5 million, primarily driven by an increase in personnel costs of €6.5 million and travel expenses of €0.7 million due to an increase in the number of employees in research and development functions, but also a €0.6 million increase in consultancy costs. General costs, such as rent and facility costs, IT costs and depreciation increased by €0.7 million. Research and development costs included non-cash share-based payment of €4.8 million for the year ended December 31, 2017, compared to €3.7 million for the year ended December 31, 2016.

General and Administrative Expenses

General and administrative expenses were €25.1 million for the year ended December 31, 2018, an increase of €11.6 million, or 86%, compared to €13.5 million for the year ended December 31, 2017. The increase is primarily due to €3.4 million higher personnel costs and €4.5 million higher non-cash share-based payment due to an increase in headcount, but also reflecting a €2.3 million increase in professional fees, including recruitment cost and initial costs of preparing to become a commercial organization. General costs including facilities, IT, and insurances, increased by a net amount of €1.4 million. General and administrative expenses included non-cash share-based payment of €9.4 million for the year ended December 31, 2018, compared to €4.9 million for the year ended December 31, 2017.

General and administrative expenses were €13.5 million for the year ended December 31, 2017, an increase of €2.0 million, or 17%, compared to €11.5 million for the year ended December 31, 2016. The increase is primarily due to an increase in personnel costs of €1.6 million, primarily related to non-cash share-based payment and an increase in investor relations, travel and other costs. General and administrative expenses included non-cash share-based payment of €4.9 million for the year ended December 31, 2017, compared to €3.6 million for the year ended December 31, 2016.

Net Profit / (Loss) in Associate

Net loss in associate was €0.3 million which represent the Company's share of net result in Visen Pharmaceuticals, a company established under the laws of the Cayman Islands on November 7, 2018.

As Visen Pharmaceuticals was established in 2018, no comparative figures are presented.

Finance Income and Finance Expenses

Finance income was €24.7 million for the year ended December 31, 2018, an increase of €23.8 million compared to €0.9 million for the year ended December 31, 2017. Finance expenses were €0.1 million for the year ended December 31, 2018, a decrease of €13.6 million compared to €13.8 million for the year ended December 31, 2017. The €37.4 million increase in net finance income was primarily due to positive exchange rate fluctuations, primarily between the U.S. Dollar and Euro over the year ended December 31, 2018, primarily affecting our cash positions maintained in U.S. Dollar. Net finance income for the year ended December 31, 2018 was also positively affected by €3.9 million in net interest income compared to €0.8 million for the year ended December 31, 2017.

Finance income was €0.9 million for the year ended December 31, 2017, a decrease of €6.4 million compared to €7.3 million for the year ended December 31, 2016. Finance expenses were €13.8 million for the year ended December 31, 2017, an increase of €10.7 million compared to €3.1 million for the year ended December 31, 2016. The €17.0 million increase in net finance expenses was due to negative exchange rate fluctuations, primarily between the U.S. Dollar and Euro in 2017, whereas the U.S. Dollar strengthened against the Euro during the year ended December 31, 2016.

The impact of exchange rate fluctuations is primarily related to our cash position in U.S. Dollar. We seek to minimize our exchange rate risk by maintaining cash positions in the currencies in which we expect to incur the majority of our budgeted future expenses and we make payments from those positions.

We did not hold interest-bearing debt for any of the periods presented.

Tax on Profit / (Loss) for the Year

Tax for the year ended December 31, 2018 was a net tax credit of €0.4 million, compared to a net tax credit of €0.5 million for the year ended December 31, 2017. Under Danish tax legislation, tax losses may be partly refunded by the tax authorities to the extent such tax losses arise from research and development activities. For the year ended December 31, 2018, the jointly taxed Danish entities had a tax loss, and accordingly were entitled to a tax refund of approximately €0.7 million. The tax for the year ended December 31, 2018 further comprised a tax provision of €0.2 million related to our subsidiary in Germany and a net tax provision of €0.1 million related to our subsidiary in the United States.

Tax for the year ended December 31, 2017 was a net tax credit of €0.5 million, compared to a net tax credit of €0.2 million for the year ended December 31, 2016. Under Danish tax legislation, tax losses may be partly refunded by the tax authorities to the extent such tax losses arise from research and development activities. For the year ended December 31, 2017, the jointly taxed Danish entities had a tax loss, and accordingly, were entitled to a tax refund of approximately €0.7 million. The tax for the year ended December 31, 2017 further comprised a tax provision of €0.3 million related to our subsidiary in Germany and a net tax credit of €0.1 million related to our subsidiary in the United States.

At December 31, 2018, 2017 and 2016, we had net deferred tax assets of €78.5 million, €52.7 million, and €27.5 million, respectively, which were not recognized in the consolidated statement of financial position due to uncertainties relating to the future utilization. The increase in the unrecognized deferred tax asset can primarily be attributed to an increase in tax losses carried forward. The deferred tax asset can be carried forward without timing limitations. For tax losses carried forward, certain limitations exist for amounts to be utilized each year.

Quantitative and Qualitative Disclosures about Market Risk

Our activities primarily expose us to the financial risks of changes in foreign currency exchange rates and interest rates. We do not enter into derivative financial instruments to manage our exposure to such risks.

Foreign Currency Risk

We are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the U.S. Dollar, the British Pound and the Danish Krone. Our functional currency is the Euro, but we have received payments in U.S. Dollars under our collaborations. Further, the proceeds from our Series D financing in November 2014, our IPO in February 2015 and our follow-on offerings in October and November 2016, in September and October 2017, in February 2018 and in March 2019 were in U.S. dollars. We seek to minimize our exchange rate risk by maintaining cash positions in the currencies in which we expect to incur the majority of our budgeted future expenses and we make payments from those positions. As required under IFRS, we perform an analysis and report on our foreign currency exposure on an annual basis. At December 31, 2018, the net carrying amount of our monetary assets and liabilities was €259.3 million, and we held $178.3 million denominated in U.S. Dollars, primarily related to the proceeds from the follow-on offering completed in February 2018.

A sensitivity analysis of our exposure to the U.S. Dollar based on outstanding foreign currency denominated monetary items as of December 31, 2018 shows that a strengthening of the U.S. Dollar against the Euro by 10% would increase net profit or loss and equity by €17.8 million. A 10% weakening of the U.S. Dollar against the Euro would decrease net profit or loss and equity by a similar amount.

A sensitivity analysis of our exposure to the U.S. Dollar based on outstanding foreign currency denominated monetary items as of December 31, 2017 shows that a strengthening of the U.S. Dollar against the Euro by 10% would increase net profit or loss and equity by €18.3 million. A 10% weakening of the U.S. Dollar against the Euro would decrease net profit or loss and equity by a similar amount.

A sensitivity analysis of our exposure to the U.S. Dollar based on outstanding foreign currency denominated monetary items as of December 31, 2016 shows that a strengthening of the U.S. Dollar against the Euro by 10% would increase net profit or loss and equity by €11.9 million. A 10% weakening of the U.S. Dollar against the Euro would decrease net profit or loss and equity by a similar amount.

Interest Rate Risk

As we have no interest-bearing debt to third parties, our exposure to interest rate risk primarily relates to the interest rates for our positions of cash, cash equivalents and marketable securities. Our future interest income from interest-bearing bank deposits and short-term investments may fall short of expectations due to changes in interest rates. We do not consider the effects of interest rate fluctuations to be a material risk to our financial position. Accordingly, no interest sensitivity analysis has been presented.

We have adopted an investment policy with the primary purpose of preserving capital, fulfilling our liquidity needs and diversifying the risks associated with marketable securities. This investment policy establishes minimum ratings for institutions with which we hold cash, cash equivalents and marketable securities, as well as rating and concentration limits for marketable securities that we may hold.

Credit Risk

We consider all of our material counterparties to be creditworthy. Our trade receivables consist of a small number of large transactions with our collaboration partners and other biopharmaceutical companies. This may lead to significant concentration of credit risk, but we consider the credit risk for each of our collaboration partners, and other customers with whom we conduct business, to be low. We limit our credit risk on cash and cash equivalents by depositing our cash reserves with banks that maintain high credit ratings assigned by international credit-rating agencies.

Liquidity Risk

We manage our liquidity risk by maintaining adequate cash reserves and banking facilities, and by continuously monitoring our cash forecasts and actual cash flows, and by matching the maturity profiles of financial assets and liabilities. Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2018 are sufficient to meet our projected cash requirements for at least 12 months from the date of this annual report.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with IFRS as issued by the IASB. A description of our accounting policies is provided in the Accounting Policies section of the audited consolidated financial statements as of and for the years ended December 31, 2018, 2017 and 2016 included elsewhere in this annual report. In the application of our accounting policies, we are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. In some instances, we could have reasonably used different accounting estimates, and in other instances changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ significantly from the estimates we have made. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial conditions, results of operations and cash flows will be affected.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision or revisions affect both current and future periods.

Critical Accounting Policies

In the application of our accounting policies, we are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The following are the critical judgments, apart from those involving estimates, made in the process of applying our accounting policies and that have the most significant effect on amounts recognized in our consolidated financial statements.

Revenue Recognition

We evaluate all our revenue generating transactions to ensure recognition in accordance with IFRS. Revenue is primarily generated from collaboration- and license agreements, which typically involve multiple promises, and thus require significant judgments by us on certain areas including:

- determining whether the promises in the agreements are distinct performance obligations;
- identifying and constraining variable consideration in the transaction price including milestone payments;
- allocating transaction price to identified performance obligations based on their relative stand-alone selling prices; and
- determining whether performance obligations are satisfied over, – or at a point in – time.

Critical judgments relating to revenue recognition are described below.

Collaboration Agreements

Identifying Performance Obligations

Our two collaboration agreements in place were entered in 2010 and 2013, respectively. The agreements include grant of licenses and contemplate our involvement in the ongoing research and development of our partnered product candidates.

At the time the collaboration agreements were entered, the product candidates were early-stage development projects, where the partnered development activities were considered single performance obligations. Accordingly, up-front fees have been recognized as revenue over time based on our continued involvement in development activities.

License Agreements

While we have not entered into new collaboration agreements with external parties since 2013, the judgments that significantly affect the determination of the amount and timing of revenue from contracts with customers relate to three license agreements, which were entered into in 2018.

Identifying Performance Obligations and Allocating Transaction Price

The three license agreements entered into in 2018 grant licensee exclusive rights to develop, manufacture, and commercialize patented product candidates in Greater China ("Territory"), including the right to grant sub-licenses to third parties. In addition to licenses, we will deliver development services and provide clinical supply material to be used in clinical trials within the Territory.

In determination of the performance obligations under the license agreements, we have considered the stand-alone values of the promises in the contracts, and our responsibility in the future development activities including bringing the licensed products to market in the Territory.

While licensed product candidates are all in phase 1 or later, we have concluded that the licensee can benefit from each promise in the contract either on their own or together with readily available resources. Thus, each of the license agreements comprise the following distinct performance obligations, licenses, development services, and clinical trial supplies, respectively.

Classification of Licenses as "Right-to-Use" or "Right-to-Access"

We have considered whether we are obligated or expected to perform research and development activities that significantly affect the licensee's ability to benefit from product candidates. If we are contractually obligated,- or if we determine that we are expected to perform research and development activities affecting the stand-alone functionality of the product candidate, the license is classified as "right-to-access". Other licenses are classified as "right-to-use".

While licensed products are patented drug formulas, our future activities do not affect their stand-alone functionalities. Accordingly, all three licenses granted in 2018 have been classified as "right-to-use", with revenue recognized at the point in time, where licensee is granted access to the intellectual property.

Share-Based Payment

IFRS 2, "Share-Based Payment" requires an entity to reflect in its profit or loss and financial position the effects of share-based payment transactions, including expenses associated with transactions in which share options are granted to employees. Share-based incentive programs under which board members, employees and external consultants have the option to purchase shares in Ascendis Pharma A/S (equity-settled share-based payment arrangements) are measured at the equity instrument's fair value at the grant date.

We use the Black-Scholes option-pricing model to calculate the fair value of the warrants granted and critical judgments need to be exercised in determining the appropriate input to the valuation model as well as to determine the appropriate way of recognizing the expenses under IFRS 2. The Black-Scholes option-pricing model is applied with the following assumptions: (1) an exercise price equal to or above the estimated market price of our shares at the date of grant; (2) an expected lifetime of the warrants determined as a weighted average of the time from grant date to date of becoming exercisable and from grant date to expiry of the warrants; (3) a risk free interest rate equaling the effective interest rate on a Danish government bond with the same lifetime as the warrants; (4) no payment of dividends; and (5) a volatility for comparable companies for a historic period equaling the expected lifetime of the warrants. The expected volatility reflects the assumption that the historical volatility over a period similar to the life of the warrants is indicative of future trends. The expected volatility has been calculated using a simple average of daily historical data of comparable publicly traded companies, as we do not have sufficient data for the volatility of our own share price.

The cost is recognized together with a corresponding increase in equity over the period in which the performance and/or service conditions are fulfilled, the vesting period. Warrants granted under our warrant programs vest on a monthly basis over periods of up to 48 months. Due to the graded vesting, the related expenses are recognized on an accelerated basis; i.e. each tranche of a warrant grant is treated separately for expense recognition purposes. Accordingly, the expenses related to each warrant grant is treated in up to 48 tranches, all being recognized over the vesting period.

Share-based payment was €19.7 million, €9.7 million and €7.3 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Internally Generated Intangible Assets

IAS 38, "Intangible Assets" prescribes that intangible assets arising from development projects must be recognized in the balance sheet if the criteria for capitalization are met. That means (1) that the development project is clearly defined and identifiable; (2) that technological feasibility, adequate resources to complete and a market for the product or an internal use of the project can be documented; (3) that the expenditure attributable to the development project can be measured reliably; and (4) that we have the intent to produce and market the product or use it internally.

Such an intangible asset shall be recognized if it can be documented that the future income from the development project will exceed the aggregate cost of development, production, sale and administration of the product.

Due to the risk associated with drug development, future income from our development projects cannot be determined with sufficient certainty until the development activities have been completed and the necessary marketing approvals have been obtained. Accordingly, we do not recognize internally generated intangible assets at this time.

Joint Arrangements / Collaboration Agreements

Collaboration agreements within our industry are often structured so that each party contributes its respective skills in the various phases of a development project. No joint control exists for such collaborations and the parties do not have any financial obligations on behalf of each other. Accordingly, neither of our current collaborations nor license agreements are considered to be joint arrangements as defined in IFRS 11, "Joint Arrangements."

Investment in Associate

On initial recognition of investments, we assess whether we have power over the enterprise. An associate is an enterprise where we have neither control or joint control, but where we have significant influence over financial and operational decisions based on judgment of the following factors:

- the contractual arrangement(s) with the other vote holders of the investee
- board representation
- rights arising from other contractual arrangements
- the Company's voting rights and rights over protective decisions.

We have analyzed the structure of our investment in VISEN Pharmaceuticals and concluded that the enterprise is classified as an associate as defined in IAS 28 "Investments in Associates and Joint Ventures".

Key Sources of Estimation Uncertainty

The following are the key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, that have a significant risk of causing a material adjustment to the carrying amount of assets and liabilities within the next financial year.

Revenue Recognition - Allocation of Transaction Price to Performance Obligations

Transaction price for license agreements comprises upfront, non-refundable, non-cash consideration. Additionally, the agreements comprise separate remuneration for clinical supplies and development services, which approximate their stand-alone-selling prices.

For two license agreements, entered in 2018, we have allocated upfront considerations to licenses and development services, respectively. While no active market exists for the licenses, we have determined the stand-alone value of the licenses according to an approximate market approach based on readily available information, which includes estimation uncertainties.

Impairment of Goodwill

Determining whether goodwill is impaired requires an estimation of the recoverable amount, being the higher of fair value less costs of disposal or value in use, of the cash-generating units to which goodwill has been allocated. The Company is determined to be a single cash-generating unit. Accordingly, the recoverable amount is determined based on an estimation of the Company's fair value less costs of disposal. We have determined the fair value of goodwill after taking into account the market value of our ADSs representing the enterprise value of the group enterprise as of the balance sheet date. No impairment loss has been recognized for the years ended December 31, 2018, 2017 or 2016. The carrying amount of goodwill as of December 31, 2018 and 2017 was €3.5 million.

Recognition of Accruals for Manufacturing and Clinical Trial Activities

Payment terms for contractual work related to development, manufacturing and clinical trial activities do not necessarily reflect the stage of completion of the individual projects and activities. Determination of the stage of completion for ongoing activities includes estimation uncertainties as future efforts to complete the specific activity may be difficult to predict. We have reviewed all significant ongoing activities at the balance sheet date to determine the stage of completion compared to the invoices received and recognized accruals for any additional costs.

Useful Lives of Property, Plant and Equipment

We review the estimated useful lives of property, plant and equipment at the end of each reporting period. We have concluded that the useful lives applied for 2018, 2017 and 2016 are appropriate.

B. Liquidity and Capital Resources

As of December 31, 2018, we had cash and cash equivalents totaling €277.9 million. We have funded our operations primarily through issuance of our preference shares, ordinary shares and convertible debt securities and payments to us under our collaboration agreements. Our expenditures are primarily related to research and development activities and general and administrative activities to support research and development. We do not have any debt to third parties.

On February 2, 2015, we announced the closing of our initial public offering, with net proceeds of $111.5 million (or €101.4 million) after deducting underwriting commissions and offering expenses. On October 24, 2016, we completed a follow-on public offering of ADSs, with net proceeds of $111.7 million (or €102.6 million), after deducting underwriters' commissions and offering expenses. On November 2, 2016, we completed the partial exercise of the underwriters' option to purchase additional ADSs, with net proceeds of $15.4 million (or €14.0 million) after deducting underwriters' commissions and offering expenses. On September 29, 2017, we completed a follow-on public offering of ADSs, with net proceeds of $126.2 million (or €106.9 million), after deducting underwriters' commissions and offering expenses. On October 5, 2017, we completed the exercise in full of the underwriters' option to purchase additional ADSs, with net proceeds of $19.0 million (or €16.2 million), after

deducting underwriters' commissions and offering expenses. On February 21, 2018, we completed a follow-on public offering of ADSs, with net proceeds of $210.8 million (or €171.2 million), after deducting underwriters' commissions and estimated offering expenses. On February 22, 2018, we completed the exercise in full of the underwriters' option to purchase additional ADSs, with net proceeds of $31.7 million (or €27.4 million) after deducting underwriters' commissions and estimated offering expenses. On March 5, 2019, we completed a follow-on public offering of ADSs, with net proceeds of $469.3 million (or €414.2 million), after deducting underwriters' commissions and estimated offering expenses. On March 14, 2019, we completed the exercise in full of the underwriters' option to purchase additional ADSs, with net proceeds of $70.5 million (or €62.7 million), after deducting underwriters' commissions and offering expenses. Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2018 will be sufficient to meet our projected cash requirements for at least 12 months from the date of this annual report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including, but not limited to:

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the achievement of development, regulatory and commercial milestones resulting in the payment to us from our collaboration partners of contractual milestone payments and the timing of receipt of such payments, if any;
- the progress, timing, scope, results and costs of our preclinical studies and clinical trials for our product candidates and manufacturing activities that have not been licensed, including the ability to enroll patients in a timely manner for clinical trials;
- the time and cost necessary to obtain regulatory approvals for our product candidates that have not been licensed and the costs of post-marketing studies that could be required by regulatory authorities;
- the manufacturing, selling and marketing costs associated with product candidates, including the cost and timing of building our sales and marketing capabilities;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the sales price and the availability of adequate third-party coverage and reimbursement for our product candidates;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the number and scope of preclinical and discovery programs that we decide to pursue or initiate;
- the potential acquisition and in-licensing of other technologies, products or assets;
- the time and cost necessary to respond to technological and market developments, including further development of our TransCon technologies;
- our progress (and the progress of our collaboration partners, if any) in the successful commercialization and co-promotion of our most advanced product candidates and our efforts to develop and commercialize our other existing product candidates; and
- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation, including costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of our product candidates.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, scale back or cease our research and development activities, preclinical studies and clinical trials for our product candidates for which we retain such responsibility and our establishment and maintenance of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

Since our inception, as of December 31, 2018, we have funded our operations through the sale of €662.0 million of our preference shares, ordinary shares and convertible debt securities, including our IPO, follow-on offerings and exercise of warrants, and we have received aggregate gross proceeds of approximately €76.5 million from collaboration partners for up-front technology licensing fees, assignment of certain intellectual property rights and for services rendered under those agreements.

The following table summarizes our cash flows for the years ended December 31, 2018, 2017 and 2016:

	Year Ended December 31,		
	2018 (EUR'000)	2017 (EUR'000)	2016 (EUR'000)
Cash flows from/(used in) operating activities	(138,802)	(95,099)	(60,179)
Cash flows from/(used in) investing activities	(2,648)	(941)	(672)
Cash flows from/(used in) financing activities	203,267	124,721	117,462
Net increase in cash and cash equivalents	**61,817**	**28,681**	**56,611**

Cash flows from/(used in) Operating Activities

Cash flows used in operating activities for the year ended December 31, 2018 was €138.8 million compared to €95.1 million for the year ended December 31, 2017. The net loss for the year ended December 31, 2018 of €130.1 million was adjusted by non-cash income of €10.5 million and non-cash charges of €0.9 million for depreciation and €19.7 million for share-based payments. Net finance income, primarily comprising exchange rate adjustments, of €24.6 million, share of loss in associate, €0.3 million, and net tax credits of €0.4 million, were reversed. The net change in working capital contributed positively to cash flow by €1.7 million, primarily comprising a €8.3 million increase in trade payables and other payables, partly offset by a €5.5 million increase in prepayments. The changes in deposits, trade receivables and other receivables contributed negatively to cash flow by a total of €1.0 million. We received net income taxes of €0.3 million and net interest income of €3.9 million for the year ended December 31, 2018.

Cash flows used in operating activities for the year ended December 31, 2017 was €95.1 million compared to €60.2 million for the year ended December 31, 2016. The net loss for the year ended December 31, 2017 of €123.9 million was adjusted by non-cash charges of €0.7 million for depreciation and €9.7 million for share-based payments. Net finance expenses, primarily comprising exchange rate adjustments, of €12.8 million and net tax credits of €0.5 million, were reversed. The net change in working capital contributed positively to cash flow by €5.0 million, primarily comprising a €10.8 million increase in trade payables and other payables, partly offset by an increase in prepayments of €4.9 million. The changes in deposits, trade receivables, other receivables and deferred income contributed negatively to cash flow by a total of €0.9 million. We received income taxes of €0.2 million and net interest income of €0.8 million for the year ended December 31, 2017.

Cash flows used in operating activities for the year ended December 31, 2016 was €60.2 million compared to €43.5 million for the year ended December 31, 2015. The net loss for the year ended December 31, 2016 was €68.5 million, which was partly offset by non-cash charges of €0.7 million for depreciation and €7.3 million for share-based payment. Further, net finance income, primarily comprising exchange rate adjustments of €4.2 million and net tax income of €0.2 million, were reversed. The net change in working capital of €4.0 million primarily comprised a €4.7 million increase in trade payables and other payables reduced by a €3.0 million decrease in deferred income. Prepayments, trade receivables and deposits contributed positively to the cash flow by a total of €2.6 million, partly offset by an increase in other receivables of €0.3 million. We received income taxes of €0.6 million and net interest income of €0.1 million for the year ended December 31, 2016.

Cash Flows used in Investing Activities

Cash flows used in investing activities for the year ended December 31, 2018 of €2.6 million was related to the acquisition of property, plant and equipment, primarily for use in the laboratories of our German facility, but also for use in our new offices in Denmark and in the U.S.

Cash flows used in investing activities for the year ended December 31, 2017 of €0.9 million was related to the acquisition of property, plant and equipment, primarily for use in the laboratories of our German facility.

Cash flows used in investing activities for the year ended December 31, 2016 of €0.7 million was related to the acquisition of property, plant and equipment, primarily for use in the laboratories of our German facility.

Cash Flows from / (used in) Financing Activities

Cash flows from financing activities for the year ended December 31, 2018 of €203.3 million were related to our follow-on offering completed in February 2018 in which we raised net proceeds of €196.9 million, and warrant exercises in April, June, September and December 2018 in which we received €6.4 million.

Cash flows from financing activities for the year ended December 31, 2017 of €124.7 million were related to our follow-on offering completed in October 2017 in which we raised net proceeds of €123.1 million, and warrant exercises in March, August, September, November and December 2017 in which we received €1.6 million.

Cash flows from financing activities for the year ended December 31, 2016 of €117.5 million were related to our follow-on offering completed in November 2016 in which we raised net proceeds of €116.6 million, and warrant exercises in April, May, September and December 2016 in which we received €0.9 million.

C. Research and Developments, Patents and Licenses, etc.

See “Item 4 B. Information on the Company—Business Overview” and “Item 5 A. Operating Results—Financial Operations Overview—Research and Development Costs.”

D. Trend Information

See “Item 5 A. Operating and Financial Review and Prospects—Operating Results.”

E. Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements or any holdings in variable interest entities.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2018:

	Payments Due by Period				
	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years	Total
Contractual Obligations:			(EUR’000)		
Operating Lease Obligations(1)	4,220	7,746	4,052	3,609	**19,627**
Total contractual obligations	4,220	7,746	4,052	3,609	**19,627**

(1) Operating Lease Obligations primarily comprise leased offices in Denmark and the United States, and leased offices and laboratories in Germany.

G. Safe harbor

See “Forward Looking Statements”.

Item 6 *Directors, Senior Management and Employees*

A. Directors and Senior Management

We have a two-tier governance structure consisting of a board of directors and an executive board. The two bodies are separate; however, Jan Møller Mikkelsen, our President and Chief Executive Officer, is represented on both our board of directors and our executive board. Our executive board is supported by the other members of our senior management. Below is a summary of relevant information concerning our board of directors, executive board and senior management.

Members of Our Board of Directors, Executive Board and Senior Management

Board of Directors

The following table sets forth information with respect to each of our current board members and their respective ages as of December 31, 2018. Our board of directors is divided into two classes for purposes of election. One class is elected at each annual meeting of shareholders to serve for a two-year term. Our board of directors currently consists of seven members. All board members are eligible for re-election once their term expires.

The business address of our board members is our registered office address at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark.

Name of Board Member	Age	Position(s)	Term Expires
Michael Wolff Jensen, L.L.M.	47	Chairman and Senior Vice President, Chief Legal Officer	2019
Lisa Bright	51	Board Member	2019
Albert Cha, M.D., Ph.D.	46	Board Member	2020
James I. Healy, M.D., Ph.D.	53	Board Member	2019
Jan Møller Mikkelsen	59	President, Chief Executive Officer, Board Member and Executive Director	2019
Birgitte Volck, M.D., Ph.D.	56	Board Member	2020
Lars Holtug	60	Board Member	2020

The following is a brief summary of the business experience of our non-employee board members.

Lisa Bright has served as a member of our board of directors since April 2017. Since July 2016, Ms. Bright has served as President International for Intercept Pharmaceuticals Europe Limited, a biopharmaceutical company. Prior to her appointment as President International, Ms. Bright held various senior leadership positions from November 2014 to July 2016 at Intercept Pharmaceuticals including Chief Commercial and Corporate Affairs Officer and Senior Vice President, Head of EUCA. During her tenure at Intercept, Ms. Bright has overseen the development of the global launch of an orphan medicine in the United States and Europe, including building the commercial organization in the United States and establishing legal affiliates and teams across Europe and Canada. Ms. Bright currently serves as a member of the board of directors of Dechra Pharmaceuticals PLC, a veterinary pharmaceutical company. From 2008 to November 2014, Ms. Bright held various leadership positions at Gilead Sciences Ltd., a biopharmaceutical company, including Vice President, Head of Government Affairs, Europe, Asia, Middle East and Australasia, Vice President and Head of HCV Launch Planning, Vice President and Head of Northern Europe and General Manager, UK and Ireland. Prior to Gilead Sciences, Ms. Bright served in various positions of increasing responsibility at GlaxoSmithKline plc from 1997 to 2006 including Vice President Commercial Planning and Operations and Vice President General Manager NZ and Vice President Head of Sales, UK and Ireland. Prior to that, Ms. Bright also worked at Sanofi from 1992 to 1996 and GlaxoSmithKline from 1989 to 1992. Ms. Bright received her B.Sc. in Pharmacology from University College London, United Kingdom.

Albert Cha, M.D., Ph.D. has served as a member of our board of directors since November 2014. In 2000, Dr. Cha joined Vivo Capital, a healthcare investment firm, where he has served in various positions, most recently as a managing partner. Dr. Cha currently serves as a member of the board of directors of Menlo Therapeutics, Inc. and KalVista Pharmaceuticals, Inc. and several privately held biotechnology and medical device companies. In addition, Dr. Cha has previously served as a member of the board of directors of Biohaven Pharmaceutical Holding Company Ltd., a publicly traded clinical-stage biopharmaceutical company; Aclaris Therapeutics, a publicly traded dermatology company; AirXpanders, a publicly traded women's health medical device company; BioForm Medical, Inc., a publicly traded medical aesthetics company; Carbylan Therapeutics, a publicly traded orthopedics company; and Sierra Oncology, Inc., a publicly traded oncology company. Dr. Cha holds a B.S. and an M.S. from Stanford University and an M.D. and a Ph.D. from the University of California at Los Angeles.

James I. Healy, M.D., Ph.D. has served as a member of our board of directors since November 2014. Dr. Healy has been a General Partner of Sofinnova Ventures, a biotech investment firm, since June 2000. Dr. Healy is currently a director of Coherus BioSciences, Inc., Iterum Therapeutics, Natera, Inc., NuCana plc, ObsEva SA, Y-Mabs Therapeutics, Inc. and one private company. Previously, he served as a board member of Auris Medical Holding AG, Amarin Corporation, Edge Therapeutics, Inc., Hyperion Therapeutics, Inc., InterMune, Inc., Anthera Pharmaceuticals, Inc., Durata Therapeutics, Inc., CoTherix, Inc., Movetis NV and several private companies. Dr. Healy holds an M.D. and a Ph.D. in Immunology from Stanford University School of Medicine and holds a B.A. in Molecular Biology and a B.A. in Scandinavian Studies from the University of California, Berkeley.

Birgitte Volck, M.D., Ph.D. has served as a member of our board of directors since May 2016. Since December 2018, Dr. Volck has served as the President R&D at AVROBIO Inc., a phase 2 clinical stage gene therapy company. From June 2016 to August 2018, Dr. Volck served as head of Research and Development, Rare Diseases for GlaxoSmithKline plc. From August 2012 to 2016, Dr. Volck served as the Chief Medical Officer and Senior Vice President of Development at Swedish Orphan Biovitrum AB, a biopharmaceutical company. From 2007 to July 2012, Dr. Volck held various positions at Amgen Inc., a biopharmaceutical company, including Executive Development Director, Bone, Neuroscience & Inflammation. Prior to Amgen, from 2004 to 2007, Dr. Volck served as Nordic Medical Director and Project Director at Genzyme A/S, a biotechnology company. From 2001 to 2004, Dr. Volck served as Head of Clinical Development and Medical Affairs at Pharmexa, a biotechnology company. From May 2017 to May 2018, Dr. Volck served as a director for Wilson Therapeutics AB, a biotechnology company. Since May 2016, Dr. Volck has served as a director for TFS International, a clinical research organization. Dr. Volck received her M.D. and Ph.D. degrees from Copenhagen University, Denmark.

Lars Holtug, M.Sc. has served as a member of our board of directors since November 2018. Mr. Holtug was a partner at PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab (“PWC”) from 1993 to 2015. Mr. Holtug also currently serves as chairman of Gaming Investment A/S, a gaming solutions provider, and its 10 subsidiaries, and of Valizo ApS, a luggage transportation service. Furthermore, Mr. Holtug serves as a board member and Audit Committee Chairman of Adform A/S, an ad serving provider. Previously, he was Chairman of PWC in Denmark from 2005 to 2009. From 2004 to 2015, Mr. Holtug was a member of the Danish Commercial Appeals Board (Erhvervsankenaevnet) and a board member of the Danish Company law association (Dansk Forening for Selskabsret). He was also a member of the Accounting Standards Board of the Federation of State Authorized Accountants in Denmark (Foreningen af Statsautoriserede Revisorer) from 1998 to 2002, and a member of the Auditing Standards Board from 1993 to 1998. Mr. Holtug holds an M.Sc. from Copenhagen Business School and is educated as a state authorized public accountant in Denmark.

Senior Management and Executive Board

The following table sets forth information with respect to each of the members of our senior management, their respective ages and their positions as of December 31, 2018. In addition to serving as members of our senior management, Mr. Mikkelsen and Mr. Smith currently serve as the members of our executive board. The business address of these members of our senior management is our registered office address at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark.

Name	Age	Position(s)
Jan Møller Mikkelsen	59	President, Chief Executive Officer, Board Member and Executive Director
Flemming Steen Jensen	57	Senior Vice President, Product Supply
Michael Wolff Jensen, L.L.M.	47	Chairman and Senior Vice President, Chief Legal Officer
Jonathan Leff, M.D.	61	Senior Vice President, Chief Medical Officer
Peter Rasmussen	50	Vice President, Finance and Principal Accounting Officer
Scott T. Smith	45	Senior Vice President, Chief Financial Officer
Lotte Sønderbjerg	57	Senior Vice President, Chief Administrative Officer
Kennett Sprogøe, Ph.D.	40	Senior Vice President, Head of Innovation and Research
Thomas A. Larson	57	Senior Vice President, Chief Commercial Officer
Juha Punnonen, M.D., Ph.D.	53	Senior Vice President, Head of Oncology
Jens Sigurd Okkels	58	Senior Vice President, Product Development

The following is a brief summary of the business experience of our senior management and executive board.

Jan Møller Mikkelsen founded Ascendis Pharma and has served as our President and Chief Executive Officer and as a member of our board of directors since December 2007. From 2002 to 2006, Mr. Mikkelsen served as President and Chief Executive Officer of LifeCycle Pharma A/S, now traded under the name Veloxis Pharmaceuticals A/S, a publicly traded biotechnology company. From 2000 to 2002, Mr. Mikkelsen was President of the Pharmaceutical Division of Maxygen, Inc. Prior to that, Mr. Mikkelsen co-founded ProFound Pharma A/S, a biopharmaceutical company that was later acquired by Maxygen, Inc., and at ProFound, he served as Co-Chief Executive Officer from 1999 to 2000. From 1988 to 1999, Mr. Mikkelsen held various positions at Novo Nordisk A/S, a global healthcare company, including Vice President of Protein Discovery. Mr. Mikkelsen currently serves as a member of the advisory board of Inspirion Delivery Technologies, a specialty pharmaceutical company. Mr. Mikkelsen received a Cand. Scient. degree in Biochemistry from the University of Odense, Denmark, and pursued his post-doctoral research at Children's Hospital in Oakland, CA.

Flemming Steen Jensen has served as our Senior Vice President, Product Supply since August 2015. Prior to this, Mr. Jensen served as Corporate Vice President for Global Pharma Consulting and Business Development and member of the management team at NNE Pharmaplan A/S, an engineering and consulting company (part of Novo Nordisk A/S), from October 2014 to July 2015. From 1999 to September 2014, Mr. Jensen served as Executive Vice President of Product Supply (Production, Supply Chain, Engineering and Maintenance, Business Improvements, Quality Assurance and Health, Safety and Environment) and member of the Board of Management of ALK-Abello A/S, a pharmaceutical company. From 1986 to 1999, Mr. Jensen held several management positions relating to Development, Manufacturing and Engineering within Novo Nordisk A/S, a pharmaceutical company. Mr. Jensen is also a member of various boards of directors and advisory boards of privately held companies in the life sciences industry. Mr. Jensen holds a M.Sc. in Pharmacy from the University of Copenhagen.

Michael Wolff Jensen, L.L.M. has served as Chairman of our board of directors since January 2008 and as our Senior Vice President, Chief Legal Counsel since June 2013. In addition, Mr. Jensen served as our Acting Chief Financial Officer from May 2008 to June 2013. From October 2010 to June 2013, Mr. Jensen served as Senior Legal Advisor and Head of Partnerships (France) for the renewable business division of Dong Energy A/S, the Danish State-owned utility company. Prior to Ascendis Pharma, Mr. Jensen served as Executive Vice President & Chief Financial Officer of Veloxis Pharmaceuticals A/S, a publicly traded biotechnology company, from 2003 to 2008. Prior to joining Veloxis, Mr. Jensen served as Senior Vice President & Chief Financial Officer of Genmab A/S, a publicly traded biotechnology company from 2000 to 2003. Mr. Jensen also currently serves as Chairman of the board of directors of two publicly traded biotechnology companies; XSpray Pharma AB and Eurocine Vaccines AB. Mr. Jensen was also elected as chairman of a Danish private sports manufacturing goods company in November 2016. Mr. Jensen received an L.L.M. degree from the University of Copenhagen.

Jonathan Leff, M.D. has served as our Chief Medical Officer since February 2016. From March 2015 until joining Ascendis Pharma, Dr. Leff consulted with various clients in the field of clinical development. Prior to joining Ascendis Pharma, Dr. Leff served as the Executive Vice President, Research and Development for InterMune, Inc., a biotechnology company, from February 2012 to March 2015. Prior to InterMune, Dr. Leff served as Chief Medical Officer from February 2011 to February 2012 at KaloBios Pharmaceuticals, Inc., a biotechnology company, and previously served as Vice President and Chief Medical Officer at Halozyme Therapeutics, Inc. from 2009 to 2010. Prior to joining Halozyme from 2007 to 2009, Dr. Leff was Vice President and Global Head of Inflammation Clinical Development at Roche. From 2002 to 2007, Dr. Leff held various positions at Amgen Inc., including Vice President, North American Medical Affairs. Dr. Leff received a B.A. in Chemistry from the University of Pennsylvania, and an M.D. from the University of Pennsylvania School of Medicine.

Peter Rasmussen has served as our Vice President, Finance and Principal Accounting Officer since March 2014 and served as our Principal Financial Officer from February 2016 to August 2016. Prior to joining Ascendis Pharma, Mr. Rasmussen worked as a financial consultant for Ascendis Pharma from October 2013 to March 2014. From June 2008 to August 2012, Mr. Rasmussen served as the Chief Financial Officer of AdvanDx, Inc., a privately held medical device company. From 2007 to 2008, prior to AdvanDx, Mr. Rasmussen served as Head of Finance at Veloxis Pharmaceuticals A/S. Mr. Rasmussen is a state-authorized public accountant in Denmark and received an M.Sc. in Business Economics and Auditing from Copenhagen Business School.

Scott T. Smith has served as our Senior Vice President and Chief Financial Officer since August 2016. Previously, Mr. Smith served as Director of the Healthcare Investment Banking Group at Wedbush Securities, from 2012 to 2016, where he led the healthcare team, and, from 2009 to 2012, Mr. Smith served as a Managing Director at Wedbush. Prior to joining Wedbush, Mr. Smith served as a Director in the Global Healthcare Investment Banking Group at Merrill Lynch where he began his career in 1995. He has also worked in sales, marketing and strategy roles for various companies, including start-ups and a Fortune Global 500 company. Mr. Smith received his M.B.A. from the Stanford University Graduate School of Business and his B.A. in Economics/Accounting-Physics from Claremont McKenna College.

Lotte Sønderbjerg has served as our Senior Vice President, Chief Administrative Officer since December 2007. Mrs. Sønderbjerg is also Managing Director of Ascendis Pharma GmbH. Prior to joining Ascendis Pharma, Ms. Sønderbjerg served as Senior Director of Human Resources and as Finance Director at Veloxis Pharmaceuticals A/S from 2003 to 2007. Prior to joining Veloxis Pharmaceuticals A/S, Ms. Sønderbjerg served as Senior Director of Finance and Human Resources at Acadia Pharmaceuticals Inc., a publicly traded biotechnology company from 1996 to 2003. Prior to her career in biotech, Ms. Sønderbjerg was the Executive Secretary for the CEO and Board of Directors of Novo Nordisk A/S. Ms. Sønderbjerg received a Masters of Arts in International Business Communications from University of Aarhus.

Kennett Sprogøe, Ph.D. has held positions of increasing responsibility at Ascendis Pharma since December 2007, including serving as our Senior Vice President, Product Innovation since January 2016, our Vice President, Product Innovation from June 2014 to December 2015 and our Director, Portfolio Development from November 2012 to May 2014. Prior to joining Ascendis Pharma, Dr. Sprogøe conducted research at the University of Copenhagen, where he applied novel hyphenated screening technologies to expedite discovery of drug leads from natural sources. Dr. Sprogøe holds a Ph.D. in Natural Products Chemistry from the University of Copenhagen and a M.Sc. in Pharmacy from the Danish University of Pharmaceutical Sciences.

Thomas A. Larson has served as our Senior Vice President and Chief Commercial Officer since April 2018. Previously, Mr. Larson was Vice President and Chief Commercial Officer at Mitsubishi Tanabe Pharma America, a pharmaceutical company, since 2016. At Mitsubishi, he established the U.S. commercial organization and successfully launched the company's first U.S. pharmaceutical product, Radicava9, the first amyotrophic lateral sclerosis (ALS) therapy approved in the U.S. in over 20 years. From 2013 to 2016, Mr. Larson was a member of the commercial team for Marathon Pharmaceuticals, a biopharmaceuticals company, where he helped build the commercial infrastructure. Prior to Marathon, he worked for Boehringer-lngelheim, a pharmaceutical company, and Johnson & Johnson, a broad based healthcare Company, where he oversaw sales activities focused on hospital and specialty markets. Mr. Larson began his career at Abbott Laboratories, a healthcare company, in 1985, where he worked in research and development, sales, market access and marketing roles of increasing responsibility over his 18-year tenure, including leadership positions in the commercial organization supporting orphan drug, hospital, biologics and specialty product launches. Mr. Larson holds a Bachelor of Science in Biochemistry from Northern Michigan University

Juha Punnonen, M.D., Ph.D. has served as our Senior Vice President and Head of Oncology since September 2018. Prior to this, Dr. Punnonen served as Executive Director, Oncology Discovery Research, at Merck & Co., Inc., a pharmaceutical company, where he coordinated preclinical research and early development programs for Merck Oncology, including external clinical collaborations for Merck's anti-PD-1 antibody, Keytruda® (pembrolizumab). Prior to his tenure at Merck, he served as CEO and Head of Research and Development at STATegics, Inc., a biotechnology company he co-founded in 2007. Prior to STATegics, Dr. Punnonen was Vice President and Head of Biology and Pharmacology at Maxygen, Inc., a company developing next-generation protein therapeutics and vaccines. He began his industry career in 1994 as a scientist with DNAX Research Institute (later Schering-Plough Biopharma and Merck Research Labs), where he had done his postdoctoral training in cytokine research. His clinical experience is in internal medicine, pediatrics and medical microbiology. Dr. Punnonen received his M.D. and Ph.D. (immunology) from the University of Turku, Finland.

Jens Sigurd Okkels, Ph.D., M.Sc. has served as our Senior Vice President, Product Development since April 2019. Prior to joining Ascendis, Dr. Okkels worked as an independent consultant at Okkels Consulting, GmbH from January 2018 to March 2019. From October 2011 to December 2017, Dr. Okkels served as Vice President, CMC Center Europe at Takeda Pharmaceutical Company Ltd., a pharmaceutical company. Prior to that, Dr. Okkels held various positions at Nycomed (acquired by Takeda Pharmaceutical) between 2005 and 2011. From 1999 to 2005, he worked as Director of Molecular Biology and Fermentation and Director of Science and Technology for Profound Pharma A/S (acquired by Maxygen Inc., a biopharmaceutical company, in 2000). From 1992 to 1999, Dr. Okkels worked in various positions at Novo Nordisk A/S, a pharmaceutical company. Dr. Okkels received his Ph.D. in Molecular Biology and Biochemistry from The Royal Veterinary and Agricultural University in Denmark and holds an M.Sc. in Biochemistry from University of Copenhagen in Denmark.

B. Compensation

Compensation of Members of Our Board of Directors and Senior Management

During 2018, Dr. Cha received board fees in the amount of €39,200 for his membership on our board and €11,760 for his tenure on the remuneration committee and the nominating and corporate governance committee, Dr. Healy received €43,120 for his membership on our board and €13,720 for his tenure on the nominating and corporate governance committee and the audit committee, Jonathan Silverstein received €12,923 for his membership on our board, which reflected his partial year of service on our board, Martin Olin received €21,986 for his membership on our board and €10,993 for his tenure on the audit committee and the remuneration committee, which reflected his partial year of service on our board, Ms. Volck received €35,280 for her membership on our board and €3,920 for her tenure on the nominating and corporate governance committee, Ms. Bright received €31,360 for her membership on our board and €11,760 for her tenure on the audit committee and the remuneration committee, and Mr. Holtug received €5,113 for his membership on our board and €2,557 for his tenure on the audit committee and the remuneration committee, which reflected his partial year of service on our board. Neither Messrs. Michael Wolff Jensen nor Mikkelsen received any compensation in respect of their service on the board. Their compensation under our senior management compensation program is described below.

On November 13, 2018, Mr. Holtug was granted 35,000 warrants with an exercise price per share of $61.00 (€54.1693) and an expiration date on November 13, 2028. On December 11, 2018, Dr. Cha, Dr. Healy, Dr. Volck and Ms. Bright were each granted 13,000 warrants, in each case with an exercise price per share of $62.17 (€54.6357) and an expiration date on December 11, 2028. The aggregate grant date fair value of the warrants granted to our board members in 2018 for their services as board members was €2,247,563.

The primary objective of our senior management's compensation program is to attract, motivate, reward and retain the managerial talent needed to achieve our business objectives. In addition, the compensation program is intended to compensate all employees at competitive market rates, while recognizing extraordinary accomplishments. Compensation arrangements for our senior management have been designed to align a portion of their compensation with the achievement of our business objectives and growth strategy. Bonus payments for our senior management are determined with respect to a given year based on quantitative and qualitative goals set for our company as a whole, as well as on an individual basis. Once the results of the year are known, bonus payments are determined at the discretion of our board and, with respect to senior management reporting to the CEO, in light of recommendations made by the CEO.

The aggregate compensation paid to our senior management who were employed by our company during 2018, consisting of Messrs. Jan Møller Mikkelsen, Scott T. Smith, Michael Wolff Jensen, Peter Rasmussen, Flemming Steen Jensen and Thomas A. Larson, Ms. Sønderbjerg and Drs. Sprogøe, Grethe Rasmussen, Leff, Rau, and Punnonen, for the fiscal year ended December 31, 2018 was approximately €15.5 million. This amount consists of: (i) short-term employee benefits including salary and other in-kind benefits of approximately €3.7 million, (ii) bonuses of €2.2 million, (iii) share-based payments of approximately €9.3 million, and (iv) post-employment and other benefits of €0.3 million. Share-based payments reflect the 2018 expenses of warrants granted in or before 2018. During 2018, the board made the following warrant grants to members of our senior management who were employed by our company during 2018:

Name	Grant Date	Shares Subject to Awards Granted	Award Exercise Price(s)	Award Expiration Date
Thomas A. Larson	April 10, 2018	100,000	$ 62.15 (€50.2791)	April 10, 2028
Thomas A. Larson	December 11, 2018	45,000	$ 62.17 (€54.6357)	December 11, 2028
Juha Punnonen	September 11, 2018	100,000	$ 63.77 (€55.0976)	September 11, 2028
Jan Møller Mikkelsen	December 11, 2018	200,000	$ 62.17 (€54.6357)	December 11, 2028
Scott T. Smith	December 11, 2018	45,000	$ 62.17 (€54.6357)	December 11, 2028
Michael Wolff Jensen	December 11, 2018	45,000	$ 62.17 (€54.6357)	December 11, 2028
Jonathan Leff	December 11, 2018	45,000	$ 62.17 (€54.6357)	December 11, 2028
Lotte Sønderbjerg	December 11, 2018	45,000	$ 62.17 (€54.6357)	December 11, 2028
Flemming Steen Jensen	December 11, 2018	45,000	$ 62.17 (€54.6357)	December 11, 2028
Kennett Sprogøe	December 11, 2018	45,000	$ 62.17 (€54.6357)	December 11, 2028
Peter Rasmussen	December 11, 2018	10,000	$ 62.17 (€54.6357)	December 11, 2028

The total amount set aside or accrued by us to provide pension, retirement or similar benefits for the members of our board of directors and members of senior management for the year ended December 31, 2018 was €0.

Senior Management Agreements

We have entered into employment or service agreements with our senior management. The employment agreement with Mr. Mikkelsen contains a termination notice period of six months for a termination by Mr. Mikkelsen and 12 months for a termination by us. It also provides that during the 12-month period following a change of control ("change in control period"), we may only terminate Mr. Mikkelsen's employment with 18 months' notice. In addition, if during the change in control period, the position and responsibilities of Mr. Mikkelsen are changed (excluding insignificant changes), Mr. Mikkelsen will be entitled to regard his employment as having been terminated by us with 12 months' notice.

The agreements with Messrs. Michael Wolff Jensen and Flemming Steen Jensen, Ms. Sønderbjerg and Dr. Grethe Rasmussen contain a termination notice period of three months for a termination by the employee and six months for a termination by us (except that in the case of Ms. Sønderbjerg and Dr. Grethe Rasmussen, the notice period may be no less than the notice required pursuant to the rules of the Danish Salaried Employees Act with the addition of two months). The agreement with Dr. Grethe Rasmussen terminates on April 30, 2019. The agreement with Mr. Peter Rasmussen contains a termination notice period of one month for a termination by the employee and three months for a termination by us (except that the notice period may be no less than the notice required pursuant to the rules of the Danish Salaried Employees Act). The agreement with Dr. Rau contains a termination notice period of six months for a termination by the employee or by us (other than in the case of a termination for good cause which does not require notice). The agreement with Dr. Sprogøe contains a termination notice period of one month for a termination by the employee and six months for a termination by us. The agreements with certain of the foregoing senior management contain post-termination non-competition covenants that generally may last for a period of 12 months post-termination and entitle the executives to their base salary, or portion thereof, during the period.

The agreements with Messrs. Smith and Larson and Drs. Leff and Punnonen provide that their employment is at-will and may be terminated by either the executive or us at any time, provided that the agreements with Mr. Larson and Dr. Punnonen contain a termination notice period of 60 days for a termination by the executive. However, the agreements provide that in the event the executive is terminated by us without "cause" or he resigns for "good reason" (each, as defined in the agreements), he will be eligible to receive continued base salary during a certain severance period following termination and continued healthcare coverage until up to the end of the month in which the severance period ends. For Mr. Smith and Dr. Leff, the severance period ends on the six-month anniversary of the date of termination; for Mr. Larson, the severance period ends on the later of the first anniversary of the effective date of his employment agreement and the six-month anniversary of the date of termination; and for Mr. Punnonen, the severance period ends on the first anniversary of the effective date of his employment agreement. In addition, for each of the executives, in the event of the executive's termination due to disability, he will be eligible to receive continued base salary and healthcare coverage for 120 days following termination, and in the event of his death, we will pay his estate a lump sum amount equal to three months of his base salary.

Warrant Incentive Program

Our employees, consultants, advisors and board members are eligible to participate in our warrant incentive program. Warrants have been issued by the general meeting or by our board of directors pursuant to valid authorizations in our articles of association and the terms and conditions have, in accordance with the Danish Companies Act, been incorporated in our articles of association as in effect from time to time. Each warrant grants the holder the right to subscribe for one ordinary share against cash payment of the exercise price. The exercise price is determined by our board of directors and historically has not been less than the estimated fair value of our ordinary shares on the date of grant. Our board of directors is authorized to issue an additional 2,538,125 warrants in the period ending December 31, 2019; however, warrants cannot be issued to the extent that outstanding and non-exercised warrants issued under that authorization are equal to 20% or more of our Company's registered share capital.

The grant of warrants to any participant is at the discretion of our board of directors and based on the recommendation of our management. The board of directors may determine the terms and conditions of the warrants issued, including exercise periods, subscription price and adjustments caused by changes to our company's situation.

Subject to earlier vesting upon the occurrence of certain exit events, warrants granted under the program as in effect since December 18, 2015 generally vest 1/48th per month from the date of grant subject to continued service for employees, consultants and initial grants to board members and 1/24th per month from the date of grant subject to continued service for subsequent grants to board members. Warrants granted under the program as in effect between December 2012 and December 18, 2015 generally vest 1/48th per month from the date of grant subject to continued service (previously 1/36th per month for employees and 1/24th per month from the date of grant for board members). With respect to employees, in the event that a holder resigns due to our breach of employment terms or we terminate the employment relationship and the holder has not given us good reason to do so, the warrants will continue to vest post-termination in accordance with the same vesting schedule. Otherwise, warrants will cease vesting upon termination of service with respect to employees, board members and consultants.

Vested warrants may be exercised during certain exercise periods each year. For 657,749 outstanding warrants, there are two annual exercise periods that continue for 21 days from and including the day after the publication of (i) the annual report notification—or if such notification is not published—the annual report and (ii) our interim report (six-month report). For these warrants, the last exercise period is 21 days from and including the day after the publication of our interim report for the first half of 2023. For 272,997 outstanding warrants granted in connection with our preference D financing, there are four annual exercise periods that continue for 21 days following the day of publication of (i) our interim report (three-month report); (ii) the annual report notification—or if such notification is not published—the annual report; (iii) our interim report (six-month report); and (iv) our interim report (nine-month report). For these warrants, the last exercise period is 21 days following the publication of our interim report (nine-month report) in 2023. For 4,680,883 outstanding warrants granted on or after December 18, 2015, there are four annual exercise periods; each exercise period begins two full trading days after the publication of the public release of our earnings data of a fiscal quarter and continues until the end of the second-to-last trading day in which quarter the relevant earnings release is published. The warrants granted on or after December 18, 2015 expire ten years after the grant date.

The table below sets forth information regarding outstanding warrants held by those members of our board of directors and senior management who assuming the exercise of warrants beneficially own 1% or more of our total outstanding ordinary shares as of March 1, 2019.

Name	Grant Date	Awards granted and outstanding	Awards granted and outstanding, but unvested as of March 1, 2019	Award Exercise Price(s)	Award Expiration Date
Jan Møller Mikkelsen	December 3, 2012	299,372	—	€ 7.9962	21 days following our interim report (six-month report) in 2023
	November 26, 2014	131,624	—	€ 6.4775	21 days following our interim report (nine-month report) in 2023
	December 18, 2015	220,000	45,834	€15.6750	December 18, 2025
	December 14, 2016	180,000	82,500	€19.4194	December 14, 2026
	December 12, 2017	200,000	141,667	€31.5995	December 12, 2027
	December 11, 2018	200,000	191,667	€54.6357	December 11, 2028

Name	Grant Date	Awards granted and outstanding	Awards granted and outstanding, but unvested as of March 1, 2019	Award Exercise Price(s)	Award Expiration Date
James I. Healy, M.D., Ph.D.	December 18, 2015	35,000	7,292	€15.6750	December 18, 2025
	December 14, 2016	15,000	—	€19.4194	December 14, 2026
	December 12, 2017	15,000	6,250	€31.5995	December 12, 2027
	December 11, 2018	13,000	11,917	€54.6357	December 11, 2028
Albert Cha, M.D., Ph.D.	December 18, 2015	35,000	7,292	€15.6750	December 18, 2025
	December 14, 2016	15,000	—	€19.4194	December 14, 2026
	December 12, 2017	15,000	6,250	€31.5995	December 12, 2027
	December 11, 2018	13,000	11,917	€54.6357	December 11, 2028

Insurance and Indemnification

According to the Danish Companies Act, the general meeting is allowed to discharge our board members and members of our senior management from liability for any particular financial year based on a resolution relating to the financial statements. This discharge means that the general meeting will discharge such board members and members of our senior management from liability to our company; however, the general meeting cannot discharge any claims by individual shareholders or other third parties.

Additionally, we have entered into agreements with our board members and members of our senior management, pursuant to which, subject to limited exceptions, we have agreed to indemnify such board members and members of our senior management from civil liability, including (i) any damages or fines payable by them as a result of an act or failure to act in the exercise of their duties currently or previously performed by them; (ii) any reasonable costs of conducting a defense against a claim; and (iii) any reasonable costs of appearing in other legal proceedings in which such individuals are involved as current or former board members or members of our senior management.

There is a risk that such agreement will be deemed void under Danish law, either because the agreement is deemed contrary to the rules on discharge of liability in the Danish Companies Act, as set forth above, because the agreement is deemed contrary to sections 19 and 23 of the Danish Act on Damages, which contain mandatory provisions on recourse claims between an employee (including members of our senior management) and the company, or because the agreement is deemed contrary to the general provisions of the Danish Contracts Act.

In addition to such indemnification, we provide our board members and senior management with directors' and officers' liability insurance.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to board members and senior management or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

C. Board Practices

Board of Directors

Our board of directors is responsible for our overall and strategic management and must ensure proper organization of our business. In addition, our board is obligated to ensure that (i) bookkeeping and financial reporting procedures are satisfactory; (ii) adequate risk management and internal control procedures have been established; (iii) our board

of directors receives ongoing information as necessary about our financial position; (iv) our executive board performs its duties properly and as directed by our board of directors; and (v) the financial resources of our company are adequate at all times, and that our company has sufficient liquidity to meet its current and future liabilities as they become due.

In performing its duties, our board of directors is required to act in the interests of our company (including our shareholders) and our associated business as a whole. Our board of directors may generally make any decisions in furtherance of our objectives that are not reserved for either the executive board or the shareholders either by virtue of the articles of association or by operation of Danish law. Typical shareholder decisions that our board of directors cannot resolve alone are: changes to the articles of association, elections of board members, elections of auditors, decisions to scrutinize our company's affairs, capital increases and decreases, payment of dividends, purchase of treasury shares, and decisions to merge, demerge or liquidate our company.

The general meeting of shareholders must elect no fewer than three and no more than 10 members to our board of directors. The board of directors is classified into two classes as nearly equal in number as possible with respect to the duration of the term in which they severally hold office. Such classes consist of one class of directors ("Class I") who were elected at the annual general meeting held in 2017 for a term expiring at the annual general meeting to be held 2019; and a second class of directors ("Class II") who were elected at the annual general meeting held in 2018 for a term expiring at the annual general meeting to be held in 2020 The shareholders shall increase or decrease the number of directors, to ensure that the two classes shall be as nearly equal in number as possible; provided, however, that no decrease shall have the effect of shortening the term of any other director. At each annual general meeting beginning in 2016, the successors of the class of directors whose term expires at that meeting shall be elected to hold office for a term expiring at the annual general meeting held in the second year following the year of their election.

Board members may be dismissed at any time at a general meeting of shareholders. A resolution by the general meeting of shareholders to appoint or dismiss board members requires a simple majority of the votes cast and there is no requirement for a specific quorum.

Under Danish corporate law, employees of companies that have employed at least 35 employees for the preceding three years are entitled to elect members of their board of directors corresponding to one-half of the members of their board of directors elected by the general meeting of shareholders. Board members elected by the employees are elected for terms of four years, and they hold the same rights and obligations as any board member elected by the shareholders. We do not currently have employee representatives on our board of directors.

Our board of directors elects its chairman. Our board of directors forms a quorum when more than half of the members of our board of directors are represented. Resolutions of our board of directors are passed by simple majority. Each board member is entitled to cast one vote. For a complete description of these board governance matters, you should refer to our articles of association, which are incorporated by reference as an exhibit to this annual report.

Our board of directors may also adopt resolutions without a meeting, provided that such resolutions are adopted in writing and submitted to all members of our board of directors and provided that no board member objects to adopting resolutions without conducting a meeting.

As a foreign private issuer, our board of directors is not required to hold regularly scheduled meetings at which only independent board members are present and we intend to comply with home country practices, which do not require executive sessions, in lieu of complying with Nasdaq Rule 5605(b)(2).

Mr. Mikkelsen and Mr. Jensen are members of our senior management and members of our board of directors and these individuals have employment agreements that provide for benefits upon termination of employment in certain circumstances. For information about such agreements, see "Item 6 B. Compensation—Senior Management Agreements."

Executive Board

Our executive board is in charge of the day-to-day management of our operations and is assisted in this respect by the other members of our senior management. The executive board must follow the guidelines and directions issued by the board of directors. Day-to-day management does not include decisions of an unusual nature or of major importance, having regard to the circumstance. Such decisions may only be made by the executive board if specifically authorized by the board of directors, unless it will cause considerable inconvenience to our company's activities to wait for authorization by the board of directors. If so, the board of directors must be notified of the decision as soon as possible.

In accordance with the exemption available to foreign private issuers under Nasdaq rules, we do not follow the requirements of the Nasdaq rules with regard to the process of nominating board members, and instead, follow Danish law and practice, in accordance with which our board of directors (or a committee thereof) is authorized to recommend to our shareholders director nominees for election. Under the Danish Companies Act, nominations for directors also may be made upon the request of any shareholder.

Director Independence

Our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise their ability to exercise independent judgment in carrying out the responsibilities of a director. As a result of this review, our board of directors determined that Lisa Bright, Albert Cha, M.D., Ph.D., James I. Healy, M.D., Ph.D., Birgitte Volck, M.D., Ph.D., and Lars Holtug, representing five of our seven directors, are "independent directors" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of Nasdaq. In making such determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining the director's independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities (if any).

Committees of the Board of Directors

We have an audit committee, a remuneration committee and a nominating and corporate governance committee. We have adopted a charter for each of these committees. Under Danish corporate law, it is not possible to delegate the decision making authority of the entire board of directors to board committees.

Audit Committee

Our audit committee consists of Lars Holtug (Chairman), Lisa Bright and James I. Healy, M.D., Ph.D. Each member satisfies the independence requirements of the Nasdaq listing standards, and Lars Holtug qualifies as an "audit committee financial expert," as defined in Item 16A of Form 20-F and as determined by our board of directors. Our audit committee oversees our accounting and financial reporting processes and the audits of our consolidated financial statements. As a foreign private issuer, we are not required to have a formal written audit committee charter that complies with Nasdaq Rule 5605(c)(1) and, although we have adopted an audit committee charter, we comply with home country practices in lieu of Nasdaq Rule 5605(c)(1). Nasdaq Rule 5605(c)(2)(A) requires that U.S. listed companies have an audit committee composed of at least three members, each of whom is an independent director, as defined in the Nasdaq rules. As a foreign private issuer, we are exempt from complying with the Nasdaq requirement to have an audit committee with at least three members, and we comply with home country practices in lieu of Nasdaq Rule 5605(c)(2)(A). However, our audit committee currently comprises three members, all of whom meet the relevant criteria for independence under Nasdaq rules and under Rule 10A-3 of the Exchange Act. Our audit committee is responsible for, among other things:

- making recommendations to our board of directors regarding the appointment by the general meeting of shareholders of our independent auditors;
- overseeing the work of the independent auditors, including making recommendations to the board of directors and resolving disagreements between the executive board and the independent auditors relating to financial reporting;
- reviewing the independence and quality control procedures of the independent auditors;
- discussing material off-balance sheet transactions, arrangements and obligations with the executive board and the independent auditors;

- reviewing all proposed related-party transactions;
- discussing the annual audited consolidated and statutory financial statements with the executive board;
- annually reviewing and reassessing the adequacy of our audit committee charter;
- meeting separately with the independent auditors to discuss critical accounting policies, recommendations on internal controls, the auditor's engagement letter and independence letter and other material written communications between the independent auditors and the executive board; and
- attending to such other matters as are specifically delegated to our audit committee by our board of directors from time to time.

Remuneration Committee

Our remuneration committee consists of Albert Cha, M.D., Ph.D. (Chairman), Lisa Bright and Lars Holtug. Each member satisfies the independence requirements of the Nasdaq listing standards. Our remuneration committee assists our board of directors in reviewing and approving or recommending our compensation structure, including all forms of compensation relating to our board of director and the executive board. As a foreign private issuer, we are not required to have a formal written remuneration committee charter that complies with Nasdaq Rule 5605(d)(1) and, although we have adopted a remuneration committee charter, we comply with home country practices in lieu of Nasdaq Rule 5605(d)(1). Our remuneration committee is responsible for, among other things:

- reviewing and making recommendations to our board of directors with respect to compensation of our executive board and members of our board of directors;
- reviewing and approving the compensation, including equity compensation, change-of-control benefits and severance arrangements, of our chief executive officer, chief financial officer and such other members of our executive board as it deems appropriate;
- overseeing and making recommendations to our board of directors regarding the evaluation of our executive board;
- reviewing periodically and making recommendations to our board of directors with respect to any incentive compensation and equity plans, programs or similar arrangements; and
- attending to such other matters as are specifically delegated to our compensation committee by our board of directors from time to time.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of James I. Healy, M.D., Ph.D. (Chairman), Albert Cha, M.D., Ph.D., and Birgitte Volck, M.D., Ph.D. Each member satisfies the independence requirements of the Nasdaq listing standards. Our nominating and corporate governance committee assists the board of directors in selecting individuals qualified to become our board members and in determining the composition of the board of directors and its committees. Our nominating and corporate governance committee is responsible for, among other things:

- recommending to our board of directors, persons to be nominated for election or re-election to our board of directors at any meeting of the shareholders;
- overseeing our board of director's annual review of its own performance and the performance of its committees; and
- considering, preparing and recommending to our board of directors a set of corporate governance guidelines.

For information on current term of office and the period during which the members of our board of directors, executive board and our senior management have served in office see "—Directors and Senior Management."

D. Employees

As of December 31, 2018, we employed 216 full-time employees, 76 of whom hold a Ph.D., M.D., or equivalent degrees. Of these full-time employees, 178 were engaged in research and development and 38 were engaged in general and administrative activities, including business and corporate development. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our employee relations to be good.

E. Share Ownership

See "Item 7 A. Major Shareholders and Related Party Transactions – Major Shareholders." Our employees are eligible to own shares of the company through a warrant incentive plan. For information on the plan, see "Item 6 B. Compensation—Warrant Incentive Plan."

Item 7 *Major Shareholders and Related Party Transactions*

A. Major Shareholders

The following table sets forth information relating to the beneficial ownership of our shares as of March 1, 2019, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding ordinary shares;
- each of our board members; and
- each member of our senior management, including members of our executive board.

The number of shares beneficially owned by each entity, person, member of our board of directors or senior management is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to subscribe for within 60 days of March 1, 2019 through the exercise of any warrants or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares owned by that person.

The percentage of shares beneficially owned is computed on the basis of 42,135,448 ordinary shares outstanding as of March 1, 2019. Ordinary shares that a person has the right to subscribe for within 60 days of March 1, 2019 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights but are not deemed outstanding for purposes of computing the percentage ownership of any other person. Additionally, a person is considered to have the right to subscribe for ordinary shares which are subject to outstanding warrants and vested within 60 days of March 1, 2019, although such warrants may only be exercised in prescribed exercise periods. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Ascendis Pharma A/S, at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark.

Name and Address of Beneficial Owner	Number of Outstanding Shares Beneficially Owned	Number of Warrants Exercisable Within 60 Days	Number of Shares Beneficially Owned	Percentage of Beneficial Ownership
Entities affiliated with OrbiMed Private Investments V, L.P.(1)	4,413,291	—	4,413,291	10.5%
Entities affiliated with FMR LLC(2)	4,203,246	—	4,203,246	9.9%
Entities affiliated with RA Capital Management, LLC(3)	4,132,442	—	4,132,442	9.8%
T. Rowe Price Associates, Inc. (4)	4,110,892	—	4,110,892	9.8%
Baker Bros. Advisors LP(5)	2,837,352	—	2,837,352	6.7%
Entities affiliated with Vivo Capital(6)	2,166,832	—	2,166,832	5.1%
Board Members and Senior Management				
Jan Møller Mikkelsen(7)	638,740	802,661	1,441,401	3.4%
Scott T. Smith(8)	—	75,000	75,000	*
Michael Wolff Jensen, L.L.M.(9)	—	137,026	137,026	*
Lotte Sønderbjerg(10)	—	141,974	141,974	*
Peter Rasmussen(11)	—	49,432	49,432	*
Jonathan Leff, M.D.(12)	—	127,500	127,500	*
Flemming Steen Jensen(13)	—	88,333	88,333	*
Kennett Sprogøe, Ph.D.(14)	—	111,430	111,430	*
Lisa Bright(15)	—	28,207	28,207	*
Thomas Larson(16)	—	28,750	28,750	*
Juha Punnonen, M.D., Ph.D.(17)	—	14,583	14,583	*
Jens Sigurd Okkels, Ph.D., M.Sc.	—	—	—	*
James I. Healy, M.D., Ph.D.(18)	1,979,514	56,332	2,035,846	4.8%
Albert Cha, M.D., Ph.D.(19)	2,166,832	56,332	2,223,164	5.3%
Birgitte Volck, M.D., Ph.D.(20)	—	51,957	51,957	*
Lars Holtug, M.Sc. (21)	—	3,645	3,645	*

* Indicates beneficial ownership of less than 1% of the total outstanding ordinary shares.

(1) Consists of (i) 2,282,315 ADSs and 1,480,976 ordinary shares held by OrbiMed Private Investment V, LP (“OPI V”) and (ii) 650,000 ADSs held by OrbiMed Partners Master Fund Limited (“OrbiMed Master Fund”) as reported by Amendment No. 10 to Schedule 13D filed with the SEC on June 15, 2018. OrbiMed Capital GP V LLC (“GP V”) is the general partner of OPI V. OrbiMed Advisors LLC (“OrbiMed Advisors”) is the sole managing member of GP V, which is the sole general partner of OPI V. OrbiMed Capital LLC (“OrbiMed Capital”) is the investment advisor to OrbiMed Master Fund. Carl L. Gordon is the managing member of and owner of a controlling interest in OrbiMed Advisors and OrbiMed Capital. By virtue of such relationships, GP V, OrbiMed Master Fund, OrbiMed Advisors, OrbiMed Capital and Mr. Gordon may be deemed to have voting and investment power with respect to the shares held by OPI V and OrbiMed Master Fund, and as a result may be deemed to have beneficial ownership of such shares. Each of GP V, OrbiMed Master Fund, OrbiMed Advisors, OrbiMed Capital, Mr. Isaly disclaims beneficial ownership of the shares held by OPI V and OrbiMed Master Fund, except to the extent of its or his pecuniary interest therein if any.

(2) Consists of an aggregate of 4,203,246 ordinary shares and ADSs beneficially owned, or that may be deemed to be beneficially owned, by FMR LLC, certain of its affiliates and other companies as reported on Amendment No. 3 to Schedule 13G filed on February 13, 2019 by FMR LLC. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company ("FMR Co"), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. FMR LLC has its principal business office at 245 Summer Street, Boston, MA 02210.

(3) Consists of 4,132,442 ADSs beneficially owned by RA Capital Management, LLC ("Capital"), as reported by Amendment No.76 to Schedule 13G filed with the SEC on February 11, 2019 by Capital and Peter Kolchinsky. Capital may be deemed a beneficial owner of the shares owned. Mr. Kolchinsky is the manager of Capital and may be deemed a beneficial owner of the shares beneficially owned by Capital. Capital and Mr. Kolchinsky have the shared power to vote and the shared power to dispose of 5,580,690 ordinary shares. Capital and Mr. Kolchinsky disclaim beneficial ownership of the shares described herein. The address of the Fund, Capital and Mr. Kolchinsky is c/o RA Capital Management, LLC, 20 Park Plaza, Suite 1200, Boston, MA 02116.

(4) Consists of 4,110,892 ordinary shares and ADSs held by T. Rowe Price Associates, Inc. ("Price Associates") as reported on Schedule 13G filed on February 14, 2019 by Price Associates. Price Associates, may be deemed to have sole power to vote over 1,187,224 shares and sole power to dispose of 4,110,892 shares. The address of Price Associates is 100 E. Pratt Street, Baltimore, Maryland 21202.

(5) Consists of (i) 2,541,884 ordinary shares and ADSs held by Baker Brothers Life Sciences, L.P. and (ii) 295,468 ordinary shares and ADSs held by 667, L.P. (together with Baker Brothers Life Sciences, L.P., the "Funds") as reported on Amendment No. 1 to Schedule 13G filed on February 13, 2019 by Baker Bros. Advisors LP (the "Adviser"), Baker Bros. Advisors (GP) LLC (the "Adviser GP"), Felix J. Baker and Julian C. Baker (collectively, "Baker Bros."). Pursuant to the management agreements, as amended, among the Adviser, the Funds and their respective general partners, the Funds' respective general partners relinquished to the Adviser all discretion and authority with respect to the investment and voting power of the securities held by the Funds, and thus the Adviser has complete and unlimited discretion and authority with respect to the Funds' investments and voting power over investments. The Adviser GP, Felix J. Baker and Julian C. Baker as principals of the Adviser GP, and the Adviser may be deemed to be beneficial owners of securities of the Issuer directly held by the Funds and may be deemed to have the power to vote or direct the vote of and the power to dispose or direct the disposition of such securities. The address of Baker Bros. is c/o Baker Bros. Advisors LP, 860 Washington Street, 3rd Floor, New York, NY 10014.

(6) Consists of (i) an aggregate of 1,760,739 ordinary shares and ADSs held by Vivo Ventures Fund VII, L.P. ("Vivo VII LP"), (ii) an aggregate of 38,373 ordinary shares and ADSs held by Vivo Ventures VII Affiliates Fund, L.P. ("Vivo VII Affiliates LP"), and (iii) an aggregate of 367,720 ordinary shares and ADSs held by Vivo Opportunity Fund, L.P. ("Vivo Opportunity LP") as reported on Amendment No. 2 to Schedule 13D/A filed on March 2, 2018 by Vivo VII LP, Vivo VII Affiliates LP and Vivo Opportunity LP. Vivo Ventures VII, LLC is the general partner of each of Vivo VII LP and Vivo VII Affiliates LP and may be deemed to have shared power to vote and shared power to dispose of the shares directly owned by Vivo VII LP and Vivo VII Affiliates LP. Vivo Opportunity, LLC is the general partner of Vivo Opportunity Fund, L.P. and be deemed to have shared power to vote and shared power to dispose of shares of the Issuer directly owned by Vivo Opportunity Fund, L.P. The managing members of Vivo Ventures VII, LLC are Drs. Albert Cha, Edgar Engleman, Frank Kung, Chen Yu and Mr. Shan Fu and may be deemed to have shared voting and dispositive power over the shares listed herein. The managing members of Vivo Opportunity, LLC are Drs. Albert Cha, Frank Kung, Gaurav Aggarwal and Mrs. Shan Fu and Michael Chang and may be deemed to have shared voting and dispositive power over the shares listed herein. The address for each of Vivo VII LP, Vivo VII Affiliates LP and Vivo Opportunity LP is c/o Vivo Capital LLC, 505 Hamilton Avenue, Suite 207, Palo Alto, CA 94301.

(7) Consists of (i) 638,740 ordinary shares held by Mr. Mikkelsen and (ii) 802,661 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Mr. Mikkelsen.

(8) Consists of (i) 75,000 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Mr. Smith.
(9) Consists of 137,026 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Mr. Jensen.
(10) Consists of 141,974 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Ms. Sønderbjerg.
(11) Consists of 49,432 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Mr. Rasmussen.
(12) Consists of 127,500 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Dr. Leff.
(13) Consists of 88,333 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Mr. Jensen.
(14) Consists of 111,430 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Dr. Sprogøe.
(15) Consists of 28,207 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Ms. Bright.
(16) Consists of 28,750 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Mr. Larson.
(17) Consists of 14,583 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Dr. Punnonen.
(18) Consists of (i) 56,332 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Dr. Healy and (ii) 1,979,514 ordinary shares and ADSs held by Sofinnova Venture Partners IX, L.P. (“SVP IX”). Sofinnova Management IX, L.L.C. (“SM IX”), the general partner of SVP IX, may be deemed to have sole power to vote and sole power to dispose of shares directly owned by SVP IX. Dr. James I. Healy, and Dr. Anand Mehra, the managing members of SM IX, may be deemed to have shared voting and investment power over the shares directly owned by SVP IX. Dr. Healy disclaims beneficial ownership over the shares held by SVP IX, except to the extent of his pecuniary interest therein. The address of SVP IX is c/o Sofinnova Ventures, Inc., 3000 Sand Hill Road, Bldg. 4, Suite 250, Menlo Park, California 94025.
(19) Consists of (i) 56,332 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Dr. Cha and (ii) securities beneficially owned by entities affiliated with Vivo Capital as set forth in footnote 6. Dr. Cha disclaims beneficial ownership of the shares beneficially owned by ViVo VII LP, except to the extent of his pecuniary interest therein.
(20) Consists of 51,957 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Dr. Volck.
(21) Consists of 3,645 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2019 by Mr. Holtug.

Record holders

As of March 1, 2019, assuming that all of our ordinary shares represented by ADSs are held by residents of the United States, approximately 98.4% of our outstanding ordinary shares were held in the United States by seven holders of record and 1.6% of our outstanding ordinary shares were held outside of the United Stated by two holders of record. At such date, there were outstanding 40,282,650 ADSs, each representing one of our ordinary shares, and in the aggregate representing 95.6% of our outstanding ordinary shares. At such date, there were four holders of record registered with the Bank of New York Mellon, depositary of the ADSs. The actual number of holders is greater than these numbers of record holders and includes beneficial owners whose ADSs are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

B. Related Party Transactions

The following is a description of related party transactions we have entered into since January 1, 2018 with any of our board members, our senior management and the owners of more than five percent of our share capital.

Employment Agreements and Warrant Grants

We have entered into employment agreements with, and issued warrants to, the members of our senior management and our independent board of directors. In addition, we are paying fees for board tenure and board committee tenure to the independent members of our board of directors. See Item 6.B. “Directors, Senior Management and Employees—Compensation” for more information.

Indemnification Agreements

We have entered into indemnification agreements with our board members and members of our senior management. See Item 6.B. “Directors, Senior Management and Employees—Compensation—Insurance and Indemnification” for a description of these indemnification agreements.

Visen Pharmaceuticals

VISEN Pharmaceuticals Formation

On November 8, 2018, we announced the formation of VISEN Pharmaceuticals, or Visen, a private entity established to develop, manufacture and commercialize our endocrinology rare disease therapies in the People’s Republic of China, Hong Kong, Macau, and Taiwan, or Greater China. In connection with the formation of Visen and pursuant to Exclusive License Agreements entered into on November 7, 2018, or the Rights Agreements, we, through certain subsidiaries, granted Visen exclusive rights to develop and commercialize therapeutic products based on our proprietary TransCon technologies which has been applied to develop novel products that release human growth hormone, parathyroid hormone or C-type natriuretic peptide in Greater China for use in all human indications, subject to certain exceptions. As consideration for the rights granted to Visen under the Rights Agreements, we, through certain subsidiaries, received 50% ownership in the outstanding shares of Visen and concurrently with the rights we granted to Visen, entities affiliated with Vivo Capital and Sofinnova Ventures, with which certain members of our board of directors are affiliated, purchased shares in Visen for an aggregate purchase price of $40,000,000 in cash.

Rights Agreements

Under the Rights Agreements, Visen must use diligent efforts to develop and commercialize licensed products in Greater China. Additionally, we and Visen will conduct certain research and development activities allocated to the respective party under a research and technical development plan, and Visen will reimburse us for costs of conducting such activities, including costs of our personnel committed to performing such activities in Greater China.

We will provide product supply to Visen for use in conducting clinical trials in Greater China pursuant to separate clinical supply agreements entered into concurrently with the Rights Agreements in accordance with the terms and conditions set forth therein. Additionally, we and Visen will negotiate in good faith the terms and conditions governing commercial supply of licensed product to Visen on the terms and conditions set forth in the Rights Agreements.

Under the Rights Agreements, we agreed not to research, develop, or commercialize competing products in Greater China, and Visen agreed not to grant certain rights under its interest in any inventions or intellectual property arising out of the activities conducted under the Rights Agreements to third parties, in each case, under the terms and conditions specified in the Rights Agreements. We will have the right to exploit inventions and intellectual property arising out of the activities conducted under the Rights Agreements outside of Greater China. Additionally, we granted Visen a right of first negotiation to develop and commercialize certain of our endocrinology products in Greater China.

The Rights Agreements continue in effect for as long as a valid claim of a licensed patent exists in Greater China. Visen may terminate a Rights Agreement for convenience, for uncured material breach by us of a Rights Agreement and for our bankruptcy or insolvency-related events. We may terminate a Rights Agreement for certain specified material breaches thereof by Visen, in the event Visen undergoes a change of control in favor of a competitor, if Visen challenges the validity of any of the licensed patents and for Visen’s bankruptcy or insolvency-related events.

Shareholders Agreement

In connection with the formation of Visen, on November 7, 2018, we entered into a Shareholders Agreement, or the Shareholders Agreement, providing for certain rights and obligations of Visen and its shareholders. Pursuant to the Shareholders Agreement, Visen and the Visen shareholders agreed to certain negotiated information and inspection rights, rights relating to registration of shares held by shareholders, pro rata rights to participate in future offerings by Visen of certain securities of Visen subject to certain limited exceptions, drag along provisions relating to a change of control of Visen, rights of first refusal and co-sale with respect to proposed sales (if any) by shareholders of Visen (including sales by us).

Pursuant to the Shareholders Agreement, we have the right to designate an individual for election to the board of directors of Visen and Visen has agreed that certain specified events (including a certain liquidation events) shall require the approval of (i) shareholders of Visen holding at least 60% of Visen's Series A preferred shares and/or (ii) certain members of the board of directors. Under the Shareholders Agreement and in connection with the formation of Visen, we have agreed to refrain from carrying out, or engaging in, the research, development, manufacture or commercialization of certain competing products in Greater China.

The Shareholders Agreement terminates by written agreement between us and an entity affiliated with Vivo Capital, and automatically terminates upon the dissolution of Visen. In addition, holders of a specified percentage of Series A preferred shares in Visen can terminate the Shareholders Agreement by written notice to the Visen upon the occurrence of certain events set forth in the Shareholders Agreement.

C. Interests of Experts and Counsel

Not applicable.

Item 8 *Financial Information*

A. Consolidated Statements and Other Financial Information

See the financial statements beginning on page F-1.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Dividends

We do not at present plan to pay cash dividends on our ordinary shares. Under Danish law, the distribution of ordinary and extraordinary dividends requires the approval of a company's shareholders at a company's general meeting. The shareholders may not distribute dividends in excess of the recommendation from the board of directors and may only pay out dividends from our distributable reserves, which are defined as results from operations carried forward and reserves that are not bound by law after deduction of loss carried forward. It is possible under Danish law to pay out interim dividends. The decision to pay out interim dividends shall be accompanied by a balance sheet, and the board of directors determine whether it will be sufficient to use the balance sheet from the annual report or if an interim balance sheet for the period from the annual report period until the interim dividend payment shall be prepared. If interim dividends are paid out later than six months following the financial year for the latest annual report, an interim balance sheet showing that there are sufficient funds shall always be prepared.

B. Significant Changes

See Note 19 to the audited consolidated financial statements included elsewhere in this annual report.

Item 9 *The Offer and Listing*

A. Offer and Listing Details

The ADS have been listed on The Nasdaq Global Select Market under the symbol “ASND” since January 28, 2015. Prior to that date, there was no public trading market for ADSs or our ordinary shares.

B. Plan of Distribution

Not applicable.

C. Markets

The ADS have been listed on The Nasdaq Global Select Market under the symbol “ASND” since January 28, 2015.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10 *Additional Information*

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Authorizations to Our Board of Directors

As of the date of this Form 20-F, our board of directors is authorized to increase the share capital as follows:

- Our board of directors is authorized to increase our share capital by up to 6,298,860 shares without pre-emptive subscription rights for existing shareholders in connection with cash contributions, debt conversion and contributions in kind, provided, however, that the capital increases are carried out at market value. This authorization is valid until May 23, 2022.
- Our board of directors is authorized to increase our share capital by up to 15,000,000 shares with pre-emptive subscription rights for existing shareholders in connection with cash contributions, provided, however, that the capital increases are carried out at market value. This authorization is valid until December 31, 2019.
- Our board of directors is authorized to issue an additional 2,483,625 warrants and to increase our share capital by up to 2,483,625 shares without pre-emptive subscription rights for existing shareholders in connection with the exercise, if any, of said warrants and to determine the terms and conditions thereof. Our board of directors cannot issue warrants pursuant to this authorization to the extent that already issued and still outstanding warrants under this authorization amount to 20% or more of our share capital. This authorization is valid until May 28, 2023.

- Our board of directors is, without pre-emptive rights for the existing shareholders, authorized to obtain loans against issuance of convertible notes which confer the right to subscribe up to 5,000,000 shares. The convertible notes shall be offered at a subscription price and a conversion price that correspond in aggregate to at least the market price of the shares at the time of the decision of our board of directors to issue the convertible notes. The loans shall be paid in cash and our board of directors shall determine the terms and conditions for the convertible notes. This authorization is valid until December 31, 2019.
- Our board of directors is authorized at one or more times to increase the Company's share capital in favor of its employees and the employees of its subsidiaries with up to nominal DKK 500,000 without pre-emptive subscription rights for the Company's shareholders. This authorization is valid until May 23, 2021.

If our board of directors exercises its authorizations in full, and all warrants and convertible debt instruments are exercised fully (not including already issued warrants), then our share capital will amount to 76,209,600 shares consisting of 76,209,600 shares with a nominal value of DKK 1 each.

At the extraordinary general meeting held on January 23, 2015, our shareholders authorized our board of directors to allow us to acquire up to 1,000,000 shares of our share capital as treasury shares at a price corresponding to +/-10% of the listed share price at the time of the acquisition. The authorization is valid until December 31, 2019. The authorization can be used to purchase treasury shares directly and/or to acquire ADSs. As of the date of this annual report, we have not used this authorization.

Owners' Register

We are obligated to maintain an owners' register (in Danish: *ejerbog*). The owners' register is maintained by Computershare A/S (Company Registration (CVR) no. 27088899), our Danish share registrar and transfer agent. It is mandatory that the owners' register is maintained within the European Union and that it is available to public authorities.

Pursuant to the Danish Companies Act, public and private limited liability companies are required to register with the Danish Business Authority information regarding shareholders who own at least 5% of the share capital or the voting rights. Pursuant to this provision, we file registrations with the Public Owners' Register of the Danish Business Authority. Shareholders that exceed the ownership threshold must notify us and we will subsequently file the information with the Danish Business Authority. Reporting is further required upon reaching thresholds of 10%, 15%, 20%, 25%, 33 1/3%, 50%, 66 2/3%, 90% and 100%.

Articles of Association and Danish Corporate Law

With respect to our articles of association, the following should be emphasized:

Objects Clause

Our corporate object, as set out in article 3 of our articles of association, is to develop ideas and preparations for the combating of disease medically, to manufacture and sell such preparations or ideas, to own shares of companies with the same objects and to perform activities in natural connection with these objects.

Summary of Provisions Regarding the Board of Directors and the Executive Board

Pursuant to our articles of association, our board of directors shall be elected by our shareholders at the general meeting and shall be composed of not less than three and no more than 10 members. With respect to the duration of the term which our board members severally hold office, the board of directors is classified into two classes as nearly equal in number as possible. Such classes consist of one class of directors ("Class I") who were elected at the annual general meeting held in 2017 for a term expiring at the annual general meeting to be held in 2019; and a second class of directors ("Class II") who were elected at the annual general meeting held in 2018 for a term expiring at the annual general meeting to be held in 2020. The shareholders shall increase or decrease the number of directors, in order to ensure that the two classes shall be as nearly equal in number as possible; provided, however,

that no decrease shall have the effect of shortening the term of any other director. At each annual general meeting beginning in 2016, the successors of the class of directors whose term expires at that meeting shall be elected to hold office for a term expiring at the annual general meeting held in the second year following the year of their election. Board members must retire from the board of directors at the annual general meeting following their 75th birthday. Board members are not required to own any shares of our share capital.

The board of directors shall appoint and employ an executive board consisting of one to five members to attend to our day-to-day management, and the board of directors shall determine the terms and conditions of the employment.

Voting Rights

Each shareholder is entitled to one vote for each share owned at the time of any general meeting. As compared with Danish citizens, there are no limitations under the articles of association or under Danish law on the rights of foreigners or non-Danish citizens to hold or vote our shares.

Dividend Rights

Our shareholders may at general meetings authorize the distribution of ordinary and extraordinary dividends. Our shareholders may not distribute dividends in excess of the recommendation from our board of directors and may only pay out dividends from our distributable reserves, which are defined as results from operations carried forward and reserves that are not bound by law after deduction of loss carried forward.

Our shareholders are eligible to receive any dividends declared and paid out. However, we have not to date declared or paid any dividends and we currently intend to retain all available financial resources and any earnings generated by our operations for use in the business and we do not anticipate paying any dividends in the foreseeable future. The payment of any dividends in the future will depend on a number of factors, including our future earnings, capital requirements, financial condition and future prospects, applicable restrictions on the payment of dividends under Danish law and other factors that our board of directors may consider relevant.

See “Item 10 E. Additional Information—Taxation” for a summary of certain tax consequences in respect of dividends or distributions to holders of our ordinary shares or the ADSs.

Pre-emptive Subscription Rights

Under Danish law, all shareholders have pre-emptive subscription rights in connection with capital increases that are carried out as cash contributions. An increase in share capital can be resolved by the shareholders at a general meeting or by the board of directors pursuant to an authorization given by the shareholders. In connection with an increase of a company’s share capital, the shareholders may, by resolution at a general meeting, approve deviations from the general Danish pre-emptive rights of the shareholders. Under the Danish Companies Act, such resolution must be adopted by the affirmative vote of shareholders holding at least a two-thirds majority of the votes cast and the share capital represented at the general meeting.

The board of directors may resolve to increase our share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations set forth above under the caption “Authorizations to Our Board of Directors.”

Unless future issuances of new shares and/or pre-emptive rights are registered under the Securities Act or with any authority outside Denmark, U.S. shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights.

Rights on Liquidation

Upon a liquidation or winding-up of our company, shareholders will be entitled to participate, in proportion to their respective shareholdings, in any surplus assets remaining after payment of our creditors.

Limitations on Holding of Shares

There are no limitations on the right to hold shares under the articles of association or Danish law.

Liability to Capital Calls by Us

Under our articles of association as well as the Danish Companies Act, our shareholders are not obligated to pay further amounts to us. All our shares are fully-paid.

Sinking Fund Provisions

There are no sinking fund provisions or similar obligations relating to our ordinary shares.

Disclosure Requirements

Pursuant to Section 55 of the Danish Companies Act, a shareholder is required to notify us when such shareholder's stake represents 5% or more of the voting rights in our company or the nominal value accounts for 5% or more of the share capital, and when a change of a holding already notified entails that the limits of 5%, 10%, 15%, 20%, 25%, 50%, 90% or 100% and the limits of one-third and two-thirds of the share capital's voting rights or nominal value are reached or are no longer reached. The notification shall be given within two weeks following the date when the limits are reached or are no longer reached.

The notification shall provide information about the full name, address or, in the case of undertakings, registered office, the number of shares and their nominal value and share classes as well as information about the basis on which the calculation of the holdings has been made. In the event that the shareholder is a non-resident company or citizen of Denmark, the notification shall include documentation, which clearly identifies the owner. The company shall cause the notification to be entered in the owners' register.

Upon the implementation of adopted legislation in Denmark, we will be obligated to collect and store for a period of at least five years certain information regarding the beneficial owners of shares in the Company. A beneficial owner is a physical person that directly or indirectly controls a shareholder. The Company shall cause such information to be registered with the Danish Business Authority.

The legal status of the notification obligations is not fully clarified in relation to ADS holders and an ADS holder may be subject to such obligations.

General Meetings

The general meeting of shareholders is the highest authority in all matters, subject to the limitations provided by Danish law and the articles of association. The annual general meeting shall be held in the Greater Copenhagen area not later than the end of May in each year.

At the annual general meeting, the audited annual report is submitted for approval, together with the proposed appropriations of profit/treatment of loss, the election of the board of directors and election of our auditors. In addition, the board of directors reports on our activities during the past year.

General meetings are convened by the board of directors with a minimum of two weeks' notice and a maximum of four weeks' notice by letter, fax or by e-mail. A convening notice will also be forwarded to shareholders recorded in our owners' register, who have requested such notification and by publication in the Danish Business Authority's computerized information system and on the company's website.

At the latest, two weeks before a general meeting (inclusive of the day of the general meeting), we shall make the following information and documents available on our webpage:

- the convening notice,
- the documents that shall be presented at the general meeting, and
- the agenda and the complete proposals.

Shareholders are entitled to attend general meetings, either in person or by proxy, and they or their proxy may be accompanied by one advisor. A shareholder's right to attend general meetings and to vote at general meetings is determined on the basis of the shares that the shareholder holds on the registration date. The registration date shall be one week before the general meeting is held. The shares which the individual shareholder holds are calculated on the registration date on the basis of the registration of ownership in the owners' register as well as notifications concerning ownership which the Company has received with a view to update the ownership in the owners' register. In addition, any shareholder who is entitled to attend a general meeting and who wishes to attend must have requested an admission card from us no later than three days in advance of the general meeting.

Any shareholder is entitled to submit proposals to be discussed at the general meetings. However, proposals by the shareholders to be considered at the annual general meeting must be submitted in writing to the board of directors not later than six weeks before the annual general meeting.

Extraordinary general meetings must be held upon resolution of an annual general meeting to hold such a meeting or upon request of the board of directors, our auditors or shareholders representing at least 1/20 of the registered share capital or such lower percentage as our articles of association may provide. Our articles of association do not state such lower percentage.

Holders of ADSs are not entitled to directly receive notices or other materials or to attend or vote at general meetings.

Resolutions in General Meetings

Resolutions made by the general meeting generally may be adopted by a simple majority of the votes cast, subject only to the mandatory provisions of the Danish Companies Act and our articles of association. Resolutions concerning all amendments to the articles of association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder's ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose or increase any obligations of the shareholders towards the company require unanimity.

Quorum Requirements

There are no quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares.

Squeeze Out

According to Section 70 of the Danish Companies Act, shares in a company may be redeemed in full or in part by a shareholder holding more than nine-tenths of the shares and the corresponding voting rights in the company. Furthermore, according to Section 73 of the Danish Companies Act, a minority shareholder may require a majority shareholder holding more than nine-tenths of the shares and the corresponding voting rights to redeem the minority shareholder's shares.

Danish Rules Intended to Prevent Market Abuse

As of July 3, 2016, EU Regulation No 596/2014 on market abuse entered into force and Chapter 10 of the Danish Securities Trading Act was repealed. Pursuant to said Chapter 10, we had adopted an internal code on inside information in respect of the holding of and carrying out of transactions by our board of directors and executive officers and employees in the shares or ADSs or in financial instruments the value of which is determined by the value of the ordinary shares or ADSs, and we had drawn up a list of those persons working for us who could have access to inside information on a regular or incidental basis and had informed such persons of the rules on insider trading and market manipulation, including the sanctions which could be imposed in the event of a violation of those rules. However, said EU Regulation No 596/2014 on market abuse imposes no such requirements on us and we have therefore taken steps to abandon our previous practice.

Limitation on Liability

Under Danish law, members of the board of directors or senior management may be held liable for damages in the event that loss is caused due to their negligence. They may be held jointly and severally liable for damages to the company and to third parties for acting in violation of the articles of association and Danish law.

According to the Danish Companies Act, the general meeting is allowed to discharge our board members and members of our senior management from liability for any particular financial year based on a resolution relating to the financial statements. This discharge means that the general meeting will discharge such board members and members of our senior management from liability to us; however, the general meeting cannot discharge any claims by individual shareholders or other third parties.

Additionally, we intend to enter, or have entered, into agreements with our board members and members of our senior management, pursuant to which, subject to limited exceptions, we will agree, or have agreed, to indemnify such board members and members of senior management from civil liability, including (i) any damages or fines payable by them as a result of an act or failure to act in the exercise of their duties currently or previously performed by them; (ii) any reasonable costs of conducting a defense against a claim; and (iii) any reasonable costs of appearing in other legal proceedings in which such individuals are involved as current or former board members or members of senior management.

There is a risk that such agreement will be deemed void under Danish law, either because the agreement is deemed contrary to the rules on discharge of liability in the Danish Companies Act, as set forth above, because the agreement is deemed contrary to sections 19 and 23 of the Danish Act on Damages, which contain mandatory provisions on recourse claims between an employee (including members of our senior management) and us, or because the agreement is deemed contrary to the general provisions of the Danish Contracts Act.

In addition to such indemnification, we provide our board members and senior management with directors' and officers' liability insurance.

Comparison of Danish Corporate Law and Our Articles of Association and Delaware Corporate Law

The following comparison between Danish corporate law, which applies to us, and Delaware corporate law, the law under which many publicly traded companies in the United States are incorporated, discusses additional matters not otherwise described in this prospectus. This summary is subject to Danish law, including the Danish Companies Act, and Delaware corporate law, including the Delaware General Corporation Law. Further, please note that ADS holders will not be treated as our shareholders and will not have any shareholder rights.

Duties of Board Members

Denmark. Public limited liability companies in Denmark are usually subject to a two-tier governance structure with the board of directors having the ultimate responsibility for the overall supervision and strategic management of the company in question and with an executive board/management being responsible for the day-to-day operations. Each board member and member of the executive board/management is under a fiduciary duty to act in the interest of the company but shall also take into account the interests of the creditors and the shareholders. Under Danish law, the members of the board of directors and executive management of a limited liability company are liable for losses caused by negligence whether shareholders, creditors or the company itself suffers such losses. They may also be liable for wrongful information given in the annual financial statements or any other public announcements from the company. An investor suing for damages is required to prove its claim with regard to negligence and causation. Danish courts, when assessing negligence, have been reluctant to impose liability unless the directors and officers neglected clear and specific duties. This is also the case when it comes to liability with regard to public offerings or liability with regard to any other public information issued by the company.

Delaware. The board of directors bears the ultimate responsibility for managing the business and affairs of a corporation. In discharging this function, directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. Delaware courts have decided that the directors of a Delaware corporation are required to exercise informed business judgment in the performance of their duties. Informed business judgment means that the directors have informed themselves of all material information reasonably

available to them. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

Terms of the Members of Our Board of Directors

Denmark. Under Danish law, the members of the board of directors of a limited liability company are generally appointed for an individual term of one year. There is no limit on the number of consecutive terms the board members may serve. Pursuant to our articles of association, our board members are appointed by the general meeting of shareholders for a term of two years and are divided into two classes. Election of board members is, according to our articles of association, an item that shall be included on the agenda for the annual general meeting.

At the general meeting, shareholders are entitled at all times to dismiss a board member by a simple majority vote.

It follows from Section 140 of the Danish Companies Act that in limited liability companies that have employed an average of at least 35 employees in the preceding three years, the employees are entitled to elect a minimum of two representatives and alternate members to the company's board of directors up to one half the number of the shareholder elected directors. If the number of representatives to be elected by the employees is not a whole number, such number must be rounded up.

Our company currently employs more than an average of 35 employees and has done so since 2016. Consequently, from 2018, our employees will be entitled to demand representation on our board of directors. The question will, upon request from the employees, be put to a popular vote among the employees. If more than half of the employees (regardless whether they participate in the vote) vote in favor of having representation, we must organize an election process.

Additionally, Section 141 of the Danish Companies Act allows for group representation on the board of directors of our Company, i.e. that employees of our Danish subsidiaries may demand representation on our board. However, our Danish subsidiaries do not currently have employees. The employees of Ascendis Pharma, Inc., and the employees of our other foreign subsidiary, Ascendis Pharma GmbH, may only demand representation on our board of directors provided that our general meeting adopts a resolution to that effect.

Delaware. The Delaware General Corporation Law generally provides for a one-year term for directors, but permits directorships to be divided into up to three classes, of relatively equal size, with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the stockholders. A director elected to serve a term on a "classified" board may not be removed by stockholders without cause. There is no limit in the number of terms a director may serve.

Board Member Vacancies

Denmark. Under Danish law, in the event of a vacancy, new board members are elected by the shareholders in a general meeting. Thus, a general meeting will have to be convened to fill a vacancy on the board of directors. However, the board of directors may choose to wait to fill vacancies until the next annual general meeting of the company, provided that the number of the remaining board members is more than two, and provided that the remaining board members can still constitute a quorum. It is only a statutory requirement to convene a general meeting to fill vacancies if the number of remaining members on the board is less than three.

Delaware. The Delaware General Corporation Law provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (1) otherwise provided in the certificate of incorporation or bylaws of the corporation or (2) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Conflict-of-Interest Transactions

Denmark. Under Danish law, board members may not take part in any matter or decision-making that involves a subject or transaction in relation to which the board member has a conflict of interest with us.

Delaware. The Delaware General Corporation Law generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- the material facts as to the director's relationship or interest are disclosed and a majority of disinterested directors' consent;
- the material facts are disclosed as to the director's relationship or interest and a majority of shares entitled to vote thereon consent; or
- the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the stockholders.

Proxy Voting by Board Members

Denmark. In the event that a board member in a Danish limited liability company is unable to participate in a board meeting, the elected alternate, if any, shall be given access to participate in the board meeting. Unless the board of directors has decided otherwise, or as otherwise is set out in the articles of association, the board member in question may grant a power of attorney to another board member, provided that this is considered safe considering the agenda in question.

Delaware. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Shareholder Rights

Notice of Meeting

Denmark. According to the Danish Companies Act, general meetings in limited liability companies shall be convened by the board of directors with a minimum of two weeks' notice and a maximum of four weeks' notice as set forth in the articles of association. A convening notice shall also be forwarded to shareholders recorded in our owners' register, who have requested such notification. There are specific requirements as to the information and documentation required to be disclosed in connection with the convening notice.

Delaware. Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.

Voting Rights

Denmark. Each ordinary share confers the right to cast one vote at the general meeting of shareholders, unless the articles of association provide otherwise. Each holder of ordinary shares may cast as many votes as it holds shares. Shares that are held by us or our direct or indirect subsidiaries do not confer the right to vote.

Delaware. Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event can a quorum consist of less than one third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than ten days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

Shareholder Proposals

Denmark. According to the Danish Companies Act, extraordinary general meetings of shareholders will be held whenever our board of directors or our appointed auditor requires. In addition, one or more shareholders representing at least 1/20th of the registered share capital of the company may, in writing, require that a general meeting be convened. If such a demand is forwarded, the board of directors shall convene the general meeting within two weeks thereafter.

All shareholders have the right to present proposals for adoption at the annual general meeting, provided that the proposals are forwarded at the latest six weeks prior thereto. In the event that the proposal is received at a later date, the board of directors will decide whether the proposal has been forwarded in due time to be included on the agenda.

Delaware. Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting of stockholders. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least $2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

Action by Written Consent

Denmark. Under Danish law, it is permissible for shareholders to take action and pass resolutions by written consent in the event of unanimity; however, this will normally not be the case in listed companies and for a listed company, this method of adopting resolutions is generally not feasible.

Delaware. Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

Appraisal Rights

Denmark. The concept of appraisal rights does not exist under Danish law, except in connection with statutory redemptions rights according to the Danish Companies Act.

According to Section 73 of the Danish Companies Act, a minority shareholder may require a majority shareholder that holds more than 90% of the company's registered share capital and votes to redeem his or her shares. Similarly, a majority shareholder holding more than 90% of the company's share capital and votes may, according to Section 70 of the same act, squeeze out the minority shareholders. In the event that the parties cannot agree to the redemption squeeze out price, this shall be determined by an independent evaluator appointed by the court. Additionally, there are specific regulations in Sections 249, 267, 285 and 305 of the Danish Companies Act that require compensation in the event of national or cross-border mergers and demergers. Moreover, shareholders who vote against a cross-border merger or demerger are, according to Sections 286 and 306 of the Danish Companies Act, entitled to have their shares redeemed.

Delaware. The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

Shareholder Suits

Denmark. Under Danish law, only a company itself can bring a civil action against a third party; an individual shareholder does not have the right to bring an action on behalf of a company. An individual shareholder may, in its own name, have an individual right to take action against such third party in the event that the cause for the liability of that third party also constitutes a negligent act directly against such individual shareholder.

Delaware. Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

Repurchase of Shares

Denmark. Danish limited liability companies may not subscribe for newly issued shares in their own capital. Such company may, however, according to the Danish Companies Act Sections 196-201, acquire fully paid shares of its own capital provided that the board of directors has been authorized thereto by the shareholders acting in a general meeting. Such authorization can only be given for a maximum period of five years and the authorization shall fix (i) the maximum value of the shares and (ii) the minimum and the highest amount that the company may pay for the shares. Shares may generally only be acquired using distributable reserves.

Delaware. Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

Anti-takeover Provisions

Denmark. Under Danish law, it is possible to implement limited protective anti-takeover measures. Such provisions may include, among other things, (i) different share classes with different voting rights, (ii) specific requirements to register the shares named in the company's owners register and (iii) notification requirements concerning participation in general meetings. We have currently not adopted any such provisions.

Delaware. In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits "business combinations," including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation's voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transaction;
- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or
- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until 12 months following its adoption.

Inspection of Books and Records

Denmark. According to Section 150 of the Danish Companies Act, a shareholder may request an inspection of the company's books regarding specific issues concerning the management of the company or specific annual reports. If approved by shareholders with simple majority, one or more investigators are elected. If the proposal is not approved by simple majority but 25% of the share capital votes in favor, then the shareholder can request the court to appoint an investigator.

Delaware. Under the Delaware General Corporation Law, any stockholder may inspect certain of the corporation's books and records, for any proper purpose, during the corporation's usual hours of business.

Pre-emptive Rights

Denmark. Under Danish law, all shareholders have pre-emptive subscription rights in connection with capital increases that are carried out as cash contributions. In connection with an increase of a company's share capital, the shareholders may, by resolution at a general meeting, approve deviations from the general Danish pre-emptive rights of the shareholders. Under the Danish Companies Act, such resolution must be adopted by the affirmative vote of shareholders holding at least a two-thirds majority of the votes cast and the share capital represented at the general meeting.

The board of directors may resolve to increase our share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations described above under the caption "Authorizations to Our Board of Directors."

Unless future issuances of new shares are registered under the Securities Act or with any authority outside Denmark, U.S. shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights.

Delaware. Under the Delaware General Corporation Law, stockholders have no pre-emptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

Dividends

Denmark. Under Danish law, the distribution of ordinary and extraordinary dividends requires the approval of a company's shareholders at a company's general meeting. The shareholders may not distribute dividends in excess of the recommendation from the board of directors and may only pay out dividends from our distributable reserves, which are defined as results from operations carried forward and reserves that are not bound by law after deduction of loss carried forward. It is possible under Danish law to pay out interim dividends. The decision to pay out interim dividends shall be accompanied by a balance sheet, and the board of directors determine whether it will be sufficient to use the balance sheet from the annual report or if an interim balance sheet for the period from the annual report period until the interim dividend payment shall be prepared. If interim dividends are paid out later than six months following the financial year for the latest annual report, an interim balance sheet showing that there are sufficient funds shall always be prepared.

Delaware. Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of shares, property or cash.

Shareholder Vote on Certain Reorganizations

Denmark. Under Danish law, all amendments to the articles of association shall be approved by the general meeting of shareholders with a minimum of two-thirds of the votes cast and two-thirds of the represented share capital. The same applies to solvent liquidations, mergers with the company as the discontinuing entity, mergers with the company as the continuing entity if shares are issued in connection therewith and demergers. Under Danish law, it is debatable whether the shareholders must approve a decision to sell all or virtually all of the company's business/assets.

Delaware. Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

However, under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, unless required by the certificate of incorporation, if (1) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (2) the shares of stock of the surviving corporation are not changed in the merger and (3) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

Amendments to Governing Documents

Denmark. All resolutions made by the general meeting may be adopted by a simple majority of the votes, subject only to the mandatory provisions of the Danish Companies Act and the articles of association. Resolutions concerning all amendments to the articles of association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder's ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose any or increase any obligations of the shareholders towards the company require unanimity.

Delaware. Under the Delaware General Corporation Law, a corporation's certificate of incorporation may be amended only if adopted and declared advisable by the board of directors and approved by a majority of the outstanding shares entitled to vote, and the bylaws may be amended with the approval of a majority of the outstanding shares entitled to vote and may, if so provided in the certificate of incorporation, also be amended by the board of directors.

C. Material Contracts

Except as otherwise disclosed in this annual report (including the Exhibits), we are not currently party to any material contract, other than contracts entered into in the ordinary course of business.

D. Exchange Controls

There are no laws or regulation in Denmark that restrict the export or import of capital (except for certain investments in certain domains in accordance with applicable resolutions by the United Nations or the European Union), including, but not limited to, foreign exchange controls, or which affect the remittance of dividends, interest or other payments to non-resident holders of our ordinary shares.

E. Taxation

Danish Tax Considerations

The following discussion describes the material Danish tax consequences under present law of an investment in the ADSs (representing our ordinary shares). The summary is for general information only and does not purport to constitute exhaustive tax or legal advice. It is specifically noted that the summary does not address all possible tax consequences relating to an investment in the ADSs. The summary is based solely on the tax laws of Denmark in effect on the date of this annual report. Danish tax laws may be subject to change, possibly with retroactive effect.

The summary does not cover investors to whom special tax rules apply, and, therefore, may not be relevant, for example, to investors subject to the Danish Tax on Pension Yields Act (*i.e.*, pension savings), professional investors, certain institutional investors, insurance companies, pension companies, banks, stockbrokers and investors with tax liability on return on pension investments. The summary does not cover taxation of individuals and companies who carry on a business of purchasing and selling shares. The summary only sets out the tax position of the direct owners of the ADSs and further assumes that the direct investors are the beneficial owners of the ADSs and any dividends thereon. Sales are assumed to be sales to a third party.

Potential investors in the ADSs are advised to consult their tax advisors regarding the applicable tax consequences of acquiring, holding and disposing of the ADSs based on their particular circumstances.

Investors who may be affected by the tax laws of other jurisdictions should consult their tax advisors with respect to the tax consequences applicable to their particular circumstances as such consequences may differ significantly from those described herein.

Taxation of Danish Tax Resident Holders of the ADSs

When considering the taxation of Danish tax resident holders of the ADSs (companies and individuals), it is assumed that for tax purposes Danish tax resident holders of the ADSs should be treated as holders of unlisted shares in the company. It is currently not clear under the Danish tax legislation or case law how the listed ADSs are to be treated for tax purposes. For the purpose of the below comments, it is assumed that the ADSs listed in the U.S. should be treated as non-listed shares as the company's ordinary shares are not admitted to trading on a regulated market.

Sale of the ADSs (Individuals)

Gains from the sale of shares are taxed as share income at a rate of 27% on the first DKK 54,000 (for cohabiting spouses, a total of DKK 108,000) and at a rate of 42% on share income exceeding DKK 54,000 (for cohabiting spouses over DKK 108,000). Such amounts are subject to annual adjustments and include all share income (*i.e.*, all capital gains and dividends derived by the individual or cohabiting spouses, respectively).

Gains and losses on the sale of shares are calculated as the difference between the purchase price and the sales price. The purchase price is generally determined using the average method (in Danish "gennemsnitsmetoden") as a proportionate part of the aggregate purchase price for all the shareholder's shares in the company.

Losses on non-listed shares may be offset against other share income, (*i.e.*, received dividends and capital gains on the sale of shares). Unused losses will automatically be offset against a cohabiting spouse's share income. In case the share income becomes negative, a negative tax on the share income will be calculated and offset against the individual's other final taxes. Unused negative tax on share income will be offset against a cohabiting spouse's final taxes. If the negative tax on share income cannot be offset against a cohabiting spouse's final taxes, the negative tax can be carried forward indefinitely and offset against future year's taxes.

Sale of the ADSs (Companies)

For the purpose of taxation of sales of shares made by shareholders (Companies), a distinction is made between Subsidiary Shares, Group Shares, Tax-Exempt Portfolio Shares and Taxable Portfolio Shares (note that the ownership threshold described below is applied on the basis of the number of all shares issued by the company, and not on the basis of the number of the ADSs issued):

"*Subsidiary Shares*" is generally defined as shares owned by a shareholder holding at least 10% of the nominal share capital of the issuing company.

"*Group Shares*" is generally defined as shares in a company in which the shareholder of the company and the issuing company are subject to Danish joint taxation or fulfill the requirements for international joint taxation under Danish law (*i.e.*, the company is controlled by the shareholder).

"*Tax-Exempt Portfolio Shares*" is defined as shares not admitted to trading on a regulated market owned by a shareholder holding less than 10% of the nominal share capital of the issuing company.

"*Taxable Portfolio Shares*" is defined as shares that do not qualify as Subsidiary Shares, Group Shares or Tax-Exempt Portfolio Shares.

Gains or losses on disposal of Subsidiary Shares and Group Shares and Tax-Exempt Portfolio Shares are not included in the taxable income of the shareholder.

Special rules apply with respect to Subsidiary Shares and Group Shares to prevent exemption through certain holding company structures just as other anti-avoidance rules may apply. These rules will not be described in further detail.

Capital gains from the sale of Taxable Portfolio Shares admitted to trading on a regulated market are taxable at a rate of 22% irrespective of ownership period. Losses on such shares are generally deductible. Gains and losses on Taxable Portfolio Shares admitted to trading on a regulated market are taxable according to the mark-to-market principle (in Danish "*lagerprincippet*").

According to the mark-to-market principle, each year's taxable gain or loss on Taxable Portfolio Shares is calculated as the difference between the market value of the shares at the beginning and end of the tax year. Thus, taxation will take place on an accrual basis even if no shares have been disposed of and no gains or losses have been realized.

If the Taxable Portfolio Shares are sold or otherwise disposed of before the end of the income year, the taxable income of that income year equals the difference between the value of the Taxable Portfolio Shares at the beginning of the income year and the value of the Taxable Portfolio Shares at realization. If the Taxable Portfolio Shares are acquired and realized in the same income year, the taxable income equals the difference between the acquisition sum and the realization sum. If the Taxable Portfolio Shares are acquired in the income year and not realized in the same income year, the taxable income equals the difference between the acquisition sum and the value of the shares at the end of the income years.

A change of status from Subsidiary Shares/Group Shares/Tax-Exempt Portfolio Shares to Taxable Portfolio Shares (or vice versa) is for tax purposes deemed to be a disposal of the shares and a reacquisition of the shares at market value at the time of change of status.

Special transitional rules apply with respect to the right to offset capital losses realized by the end of the 2009 income year against taxable gains on shares in the 2010 income year or later.

Dividends (Individuals)

Dividends paid to individuals who are tax residents of Denmark are taxed as share income, as described above. All share income must be included when calculating whether the amounts mentioned above are exceeded. Dividends paid to individuals are generally subject to 27% withholding tax.

Dividends (Companies)

Dividends paid on Subsidiary Shares and Group Shares are tax-exempt irrespective of ownership period.

Dividends paid on Tax-Exempt Portfolio Shares are partly taxable as 70% of the dividends received are included in the taxable income, which is equivalent to an effective taxation of 15.4% (70% of 22%) irrespective of ownership period.

Dividends paid on Taxable Portfolio Shares are subject to the standard corporation tax rate of 22% irrespective of ownership period.

The actual withholding tax rate is as a starting point 27%, while it can be reduced (0%, 15.4%, 22%) if certain requirements are met. A claim for repayment can be made within 2 months or the excess tax will offset the corporation income tax for the year.

Taxation of Shareholders Residing Outside Denmark

Sale of the ADSs (Individuals and Companies)

Holders of the ADSs not resident in Denmark are normally not subject to Danish taxation on any gains realized on the sale of shares, irrespective of the ownership period, subject to certain anti-avoidance rules seeking to prevent that taxable dividend payments are converted to tax exempt capital gains. If an investor holds the ADSs in connection with a trade or business conducted from a permanent establishment in Denmark, gains on shares may be included in the taxable income of such activities pursuant to the rules applying to Danish tax residents as described above.

Dividends (Individuals)

Under Danish law, dividends paid in respect of shares are generally subject to Danish withholding tax at a rate of 27%. Non-residents of Denmark are not subject to additional Danish income tax in respect to dividends received on shares.

If the withholding tax rate applied is higher than the applicable final tax rate for the shareholder, a request for a refund of Danish tax in excess hereof can be made by the shareholder in the following situations:

Reduction according to a tax treaty

In the event that the shareholder is a resident of a state with which Denmark has entered into a tax treaty, the shareholder may generally, through certain certification procedures, seek a refund from the Danish tax authorities of the tax withheld in excess of the applicable treaty rate, which is typically 15%. Denmark has entered into tax treaties with approximately 80 countries, including the United States, Switzerland and almost all members of the European Union. The tax treaty between Denmark and the United States generally provides for a 15% tax rate.

Reduction according to Danish tax law

If the shareholder holds less than 10% of the nominal share capital (in the form of ordinary shares in the company and not on the basis of the number of the ADSs issued) of the company and the shareholder is tax resident in a state which has a tax treaty or an international agreement, convention or other administrative agreement on assistance in tax matters according to which the competent authority in the state of the shareholder is obligated to exchange information with Denmark, dividends are subject to tax at a rate of 15%. If the shareholder is tax resident outside the European Union, it is an additional requirement for eligibility for the 15% tax rate that the shareholder together with related shareholders holds less than 10% of the nominal share capital of the company.

Note that the reduced tax rate does not affect the withholding rate, which is why the shareholder must claim a refund as described above in order to benefit from the reduced rate.

Where a non-resident of Denmark holds shares which can be attributed to a permanent establishment in Denmark, dividends are taxable pursuant to the rules applying to Danish tax residents described above.

Dividends (Companies)

Dividends from Subsidiary Shares are tax exempt provided that the taxation of the dividends is to be waived or reduced in accordance with the Parent-Subsidiary Directive (2011/96/EEC) or in accordance with a tax treaty with the jurisdiction in which the company investor is resident. If Denmark is to reduce taxation of dividends to a foreign company under a tax treaty, Denmark will not—as a matter of domestic law—exercise such right and will in general not impose any tax at all. Further, dividends from Group Shares—not also being Subsidiary Shares—are exempt from Danish tax provided the company investor is a resident of the European Union or the EEA and provided the taxation of dividends should have been waived or reduced in accordance with the Parent-Subsidiary Directive (2011/96/EEC) or in accordance with a tax treaty with the country in which the company investor is resident had the shares been Subsidiary Shares.

Dividends paid on both Tax-Exempt and Taxable Portfolio Shares are generally subject to tax at a rate of 22% irrespective of ownership period. While the actual withholding tax rate is as a starting point 27%, it can be reduced if certain requirements are met. If the withholding tax rate applied is higher than the applicable final tax rate for the shareholder, a request for a refund of Danish tax in excess hereof can be made by the shareholder in the following situations:

Reduction according to a tax treaty

In the event that the shareholder is a resident of a state with which Denmark has entered into a tax treaty, the shareholder may generally, through certain certification procedures, seek a refund from the Danish tax authorities of the tax withheld in excess of the applicable treaty rate, which is typically 15%. Denmark has entered into tax treaties with approximately 80 countries, including the United States and almost all members of the European Union. The tax treaty between Denmark and the United States generally provides for a 15% rate.

Reduction according to Danish tax law

If the shareholder holds less than 10% of the nominal share capital (in the form of ordinary shares in the company and not on the basis of the number of the ADSs issued) in the company and the shareholder is resident in a jurisdiction which has a tax treaty or an international agreement, convention or other administrative agreement on assistance in tax according to which the competent authority in the state of the shareholder is obligated to exchange information with Denmark, dividends are generally subject to a tax rate of 15%. If the shareholder is tax resident outside the European Union, it is an additional requirement for eligibility for the 15% tax rate that the shareholder together with related shareholders holds less than 10% of the nominal share capital of the company. Note that the reduced tax rate does not affect the withholding rate, hence, in this situation the shareholder must also in this situation claim a refund as described above in order to benefit from the reduced rate.

Where a non-resident company of Denmark holds shares which can be attributed to a permanent establishment in Denmark, dividends are taxable pursuant to the rules applying to Danish tax residents described above.

Share Transfer Tax and Stamp Duties

No Danish share transfer tax or stamp duties are payable on transfer of the shares.

Material U.S. Federal Income Tax Consequences to U.S. Holders

The following discussion describes the material U.S. federal income tax consequences to U.S. Holders (as defined below) under present law of an investment in the ADSs. The effects of any applicable state or local laws, or other U.S. federal tax laws such as estate and gift tax laws, or the Medicare contribution tax on net investment income, are not discussed. This summary applies only to investors who hold the ADSs as capital assets (generally, property held for investment) and who have the U.S. dollar as their functional currency. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury regulations promulgated thereunder, judicial decisions, published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, and the income tax treaty between the United States and Denmark, or the Treaty, all as in effect as of the date of this annual report. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below.

The following discussion does not address all U.S. federal income tax consequences relevant to a holder's particular circumstances or to holders subject to particular rules, including:

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons whose functional currency is not the U.S. dollar;
- persons holding the ADSs as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities, commodities or currencies;
- partnerships, S corporations or other entities or arrangements treated as partnerships for U.S. federal income tax purposes;
- tax-exempt organizations or governmental organizations;
- persons who acquired the ADSs pursuant to the exercise of any employee share option or otherwise as compensation;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the ADSs being taken into account in an "applicable financial statement" (as defined in the Code);
- persons that own or are deemed to own 10% or more of our equity by vote or value;
- persons that hold their ADSs through a permanent establishment or fixed base outside the United States; and
- persons deemed to sell the ADSs under the constructive sale provisions of the Code.

U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE U.S. STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF THE ADSs.

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of the ADSs that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or

- a trust that (1) is subject to the supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

If you are a partner in a partnership (or other entity taxable as a partnership for U.S. federal income tax purposes) that holds the ADSs, your tax treatment generally will depend on your status and the activities of the partnership. Partnerships holding the ADSs and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences applicable to them.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Generally, a holder of an ADS should be treated for the U.S. federal income tax purposes as holding the ordinary shares represented by the ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares. The U.S. Treasury has expressed concerns that intermediaries in the chain of ownership between the holder of an ADS and the issuer of the security underlying the ADS may be taking actions that are inconsistent with the beneficial ownership of the underlying security. Accordingly, the creditability of foreign taxes, if any, as described below, could be affected by actions taken by intermediaries in the chain of ownership between the holders of ADSs and our company if as a result of such actions the holders of ADSs are not properly treated as beneficial owners of underlying ordinary shares.

Taxation of Dividends and Other Distributions on the ADSs

Subject to the PFIC rules discussed below, the gross amount of any distribution to you with respect to the ADSs will be included in your gross income as dividend income when actually or constructively received to the extent that the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent the amount of the distribution exceeds our current and accumulated earnings and profits, it will be treated first as a return of your tax basis in the ADSs, and to the extent the amount of the distribution exceeds your tax basis, the excess will be taxed as capital gain. We do not intend to calculate our earnings and profits under U.S. federal income tax principles. Therefore, a U.S. Holder should expect a distribution will generally be reported as ordinary dividend income for such purposes. Any dividends will not be eligible for the dividends-received deduction allowed to corporations in respect of dividends received from other U.S. corporations.

If we are eligible for benefits under the Treaty, dividends a U.S. Holder receives from us generally will be "qualified dividend income." If certain holding period and other requirements, including a requirement that we are not a PFIC in the year of the dividend or the immediately preceding year, are met, qualified dividend income of an individual or other non-corporate U.S. Holder generally will be subject to preferential tax rates. You should consult your tax advisor regarding the availability of these preferential tax rates under your particular circumstances.

As discussed in "Taxation—Danish Tax Considerations," payments of dividends by us may be subject to Danish withholding tax. The rate of withholding tax applicable to U.S. Holders that are eligible for benefits under the Treaty is reduced to a maximum of 15%. For U.S. federal income tax purposes, U.S. Holders will be treated as having received the amount of Danish taxes withheld by us, and as then having paid over the withheld taxes to the Danish taxing authorities. As a result of this rule, the amount of dividend income included in gross income for U.S. federal income tax purposes by a U.S. Holder with respect to a payment of dividends may be greater than the amount of cash actually received (or receivable) by the U.S. Holder from us with respect to the payment.

Dividends will generally constitute foreign source income for foreign tax credit limitation purposes. Subject to the discussion of the PFIC rules below, any tax withheld with respect to distributions on the ADSs at the rate applicable to a U.S. Holder may, subject to a number of complex limitations, be claimed as a foreign tax credit against such U.S. Holder's U.S. federal income tax liability or may be claimed as a deduction for U.S. federal income tax purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to the ADSs generally will constitute "passive category income." The rules with respect to the foreign tax credit are complex and involve the application of rules that depend upon a U.S. Holder's particular circumstances. You are urged to consult your tax advisor regarding the availability of the foreign tax credit under your particular circumstances.

Taxation of Disposition of the ADSs

Subject to the PFIC rules discussed below, you will recognize gain or loss on any sale, exchange or other taxable disposition of an ADS equal to the difference between the amount realized (in U.S. dollars) on the disposition of the ADS and your tax basis (in U.S. dollars) in the ADS. Any such gain or loss will be capital gain or loss, and will be long-term capital gain or loss if you have held the ADS for more than one year at the time of sale, exchange or other taxable disposition. Otherwise, such gain or loss will be short-term capital gain or loss. Long-term capital gains recognized by certain non-corporate U.S. Holders, including individuals, generally will be taxable at a reduced rate. The deductibility of capital losses is subject to limitations. Any such gain or loss you recognize generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes. You should consult your tax advisor regarding the proper treatment of gain or loss in your particular circumstances.

Passive Foreign Investment Company

Based on the market price of the ADSs and the value and composition of our income and assets, we do not believe we were a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2018. However, the application of the PFIC rules is subject to uncertainty in several respects, and we cannot assure you we will not be a PFIC for any taxable year. A non-U.S. corporation is considered a PFIC for any taxable year if either:

- at least 75% of its gross income for such taxable year is passive income, or
- at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income.

For purposes of the above calculations, if a non-U.S. corporation owns, directly or indirectly, 25% or more of the total value of the outstanding shares of another corporation, it will be treated as if it (a) held a proportionate share of the assets of such other corporation and (b) received directly a proportionate share of the income of such other corporation. Passive income generally includes dividends, interest, rents, royalties and capital gains, but generally excludes rents and royalties which are derived in the active conduct of a trade or business and which are received from a person other than a related person.

A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). Because the value of our assets for purposes of the asset test will generally be determined by reference to the market price of the ADSs, our PFIC status will depend in large part on the market price of the ADSs, which may fluctuate significantly. In addition, changes in the composition of our income or assets may cause us to become a PFIC.

If we are a PFIC for any year during which you hold the ADSs, we generally will continue to be treated as a PFIC with respect to you for all succeeding years during which you hold the ADSs, unless we cease to be a PFIC and you make a “deemed sale” election with respect to the ADSs you hold. If such election is made, you will be deemed to have sold the ADSs you hold at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be subject to the consequences described below. After the deemed sale election, the ADSs with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

For each taxable year we are treated as a PFIC with respect to you, you will be subject to special tax rules with respect to any “excess distribution” (as defined below) you receive and any gain you realize from a sale or other disposition (including a pledge) of the ADSs, unless you make a “mark-to-market” election as discussed below. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for the ADSs will be treated as an “excess distribution.” Under these special tax rules, if you receive any “excess distribution” or realize any gain from a sale or other disposition of the ADSs:

- the “excess distribution” or gain will be allocated ratably over your holding period for the ADSs,
- the amount allocated to the current taxable year, and any taxable year before the first taxable year in which we were a PFIC, will be treated as ordinary income, and

- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

Gains (but not losses) realized on the sale of the ADSs cannot be treated as capital, even if you hold the ADSs as capital assets.

If we are treated as a PFIC with respect to you for any taxable year, to the extent any of our subsidiaries are also PFICs, you will be deemed to own your proportionate share of any such lower-tier PFIC, and you may be subject to the rules described in the preceding two paragraphs with respect to the shares of such lower-tier PFICs you would be deemed to own. As a result, you may incur liability for any "excess distribution" described above if we receive a distribution from such lower-tier PFICs or if any shares in such lower-tier PFICs are disposed of (or deemed disposed of). You should consult your tax advisor regarding the application of the PFIC rules to any of our subsidiaries.

Alternatively, a U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a "mark-to-market" election for such stock to elect out of the general tax treatment for PFICs discussed above. If you make a "mark-to-market" election for the ADSs, you will include in income for each year we are a PFIC an amount equal to the excess, if any, of the fair market value of the ADSs as of the close of your taxable year over your adjusted basis in such ADSs. You are allowed a deduction for the excess, if any, of the adjusted basis of the ADSs over their fair market value as of the close of the taxable year. However, deductions are allowable only to the extent of any net "mark-to-market" gains on the ADSs included in your income for prior taxable years. Amounts included in your income under a "mark-to-market" election, as well as gain on the actual sale or other disposition of the ADSs, are treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any "mark-to-market" loss on the ADSs, as well as to any loss realized on the actual sale or disposition of the ADSs to the extent the amount of such loss does not exceed the net "mark-to-market" gains previously included for the ADSs. Your basis in the ADSs will be adjusted to reflect any such income or loss amounts. If you make a valid "mark-to-market" election, the tax rules that apply to distributions by corporations that are not PFICs would apply to distributions by us, except the lower applicable tax rate for qualified dividend income would not apply. If we cease to be a PFIC when you have a "mark-to-market" election in effect, gain or loss realized by you on the sale of the ADSs will be a capital gain or loss and taxed in the manner described above under "Taxation of Disposition of the ADSs."

The "mark-to-market" election is available only for "marketable stock," which is stock that is traded in other than *de minimis* quantities on at least 15 days during each calendar quarter, or regularly traded, on a qualified exchange or other market, as defined in applicable U.S. Treasury regulations. Any trades that have as their principal purpose meeting this requirement will be disregarded. The ADSs have been approved for listing on The Nasdaq Global Select Market and, accordingly, provided the ADSs are regularly traded, if you are a holder of ADSs, the "mark-to-market" election would be available to you if we are a PFIC. Once made, the election cannot be revoked without the consent of the IRS unless the ADSs cease to be "marketable stock." If we are a PFIC for any year in which the U.S. Holder owns ADSs but before a "mark-to-market" election is made, the interest charge rules described above will apply to any "mark-to-market" gain recognized in the year the election is made. If any of our subsidiaries are or become PFICs, the "mark-to-market" election will not be available with respect to the shares of such subsidiaries that are treated as owned by you. Consequently, you could be subject to the PFIC rules with respect to income of the lower-tier PFICs the value of which already had been taken into account indirectly via "mark-to-market" adjustments. A U.S. Holder should consult its tax advisors as to the availability and desirability of a "mark-to-market" election, as well as the impact of such election on interests in any lower-tier PFICs.

In certain circumstances, a U.S. Holder of stock in a PFIC can make a "qualified electing fund election" to mitigate some of the adverse tax consequences of holding stock in a PFIC by including in income its share of the corporation's income on a current basis. However, we do not currently intend to prepare or provide the information that would enable you to make a "qualified electing fund election."

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules, taking into account the uncertainty as to whether we are currently treated as or may become a PFIC.

YOU ARE STRONGLY URGED TO CONSULT YOUR TAX ADVISOR REGARDING THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE ADSs.

Information Reporting and Backup Withholding

Dividend payments with respect to the ADSs and proceeds from the sale, exchange or other disposition of the ADSs may be subject to information reporting to the IRS and U.S. backup withholding. Certain U.S. Holders are exempt from backup withholding, including corporations and certain tax-exempt organizations. A U.S. Holder will be subject to backup withholding if such holder is not otherwise exempt and such holder:

- fails to furnish the holder's taxpayer identification number, which for an individual is ordinarily his or her social security number;
- furnishes an incorrect taxpayer identification number;
- is notified by the IRS that the holder previously failed to properly report payments of interest or dividends; or
- fails to certify under penalties of perjury that the holder has furnished a correct taxpayer identification number and that the IRS has not notified the holder that the holder is subject to backup withholding.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against the U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. U.S. Holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

Additional Reporting Requirements

Tax return disclosure obligations (and related penalties for failure to disclose) apply to certain U.S. Holders who hold certain specified foreign financial assets in excess of certain thresholds. The definition of specified foreign financial assets includes not only financial accounts maintained in foreign financial institutions, but also may include the ADSs. U.S. Holders should consult their tax advisors regarding the possible implications of these tax return disclosure obligations.

F. Dividends and Paying Agents

Not applicable.

G. Statements by Experts

Not applicable.

H. Documents on Display

We are subject to the periodic reporting and other informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under the Exchange Act, we are required to file reports and other information with the SEC. Specifically, we are required to file annually a Form 20-F no later than four months after the close of each fiscal year, which is December 31. The SEC maintains a web site at www.sec.gov that contains reports, proxy and information statements, and other information regarding registrants that make electronic filings with the SEC using its EDGAR system. As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the furnishing and content of quarterly reports and proxy statements, and officers, directors and major shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

I. Subsidiary Information

Not applicable.

Item 11 *Quantitative and Qualitative Disclosures About Market Risk*

See "Item 5 Operating and Financial Review and Prospects—Quantitative and Qualitative Disclosures about Market Risk."

Item 12 *Description of Securities Other than Equity Securities*

A. Debt Securities.

Not applicable.

B. Warrants and Rights.

Not applicable.

C. Other Securities.

Not applicable.

D. American Depositary Shares.

The Bank of New York Mellon, as depositary, registers and delivers American Depositary Shares, also referred to as ADSs. Each ADS represents one ordinary share (or a right to receive one ordinary share) deposited with The Bank of New York Mellon, London Branch, or any successor, as custodian for the depositary. Each ADS also represents any other securities, cash or other property which may be held by the depositary in respect of the depositary facility. The depositary's corporate trust office at which the ADSs are administered and its principal executive office is located at 240 Greenwich Street, New York, New York 10286.

A deposit agreement among us, the depositary and you the ADS holders sets out ADS holder rights as well as the rights and obligations of the depositary. A copy of the Agreement is incorporated by reference as an exhibit to this annual report.

Fees and Expenses

Pursuant to the terms of the deposit agreement, the holders of ADSs will be required to pay the following fees:

Persons depositing or withdrawing ordinary shares or ADSs must pay:	***For:***
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	• Issue of ADSs, including issues resulting from a distribution of ordinary shares or rights or other property • Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$0.05 (or less) per ADS	• Any cash distribution to you
A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the shares had been deposited for issue of ADSs	• Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to you
$0.05 (or less) per ADS per calendar year	• Depositary services
Registration or transfer fees	• Transfer and registration of ordinary shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	• Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement)

	• Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian have to pay on any ADS or share underlying an ADS, for example, share transfer taxes, stamp duty or withholding taxes	• As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	• As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing ordinary shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide for-fee services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse or share revenue from the fees collected from ADS holders, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the ADS program. In performing its duties under the deposit agreement, the depositary may use brokers, dealers or other service providers that are affiliates of the depositary and that may earn or share fees or commissions.

PART II

Item 13 *Defaults, Dividend Arrearages and Delinquencies*

Not applicable.

Item 14 *Material Modification to the Rights of Security Holders and Use of Proceeds*

A. Material Modifications to the Rights of Securities Holders

Not applicable.

B. Use of Proceeds

Not applicable.

Item 15 *Control and Procedures*

A. Disclosure Controls and Procedures

Our chief executive officer and principal financial and accounting officers, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of December 31, 2018, have concluded that based on the evaluation of these controls and procedures required by Rule 13a-15(b) of the Exchange Act, our disclosure controls and procedures were effective.

B. Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting.

Internal control over financial reporting is defined in rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (2) provide reasonable

assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the audited consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect material misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. This assessment was performed under the directions and supervision of our Chief Executive Officer and our principal financial and accounting officers and based on the criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission.

A material weakness is a control deficiency, or a combination of control deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected. These control deficiencies could result in a misstatement of the financial statement accounts or related disclosures that would result in a material misstatement in the annual or interim consolidated financial statements that would not be prevented or detected on a timely basis. Based on management's assessment of those criteria, management has concluded that the design and operating effectiveness of our internal control over financial reporting was effective as of December 31, 2018.

The effectiveness of the Company's internal control over financial reporting has been audited by Deloitte Statsautoriseret Revisionspartnerselskab, our independent registered public accounting firm, as stated in their report on the Company's internal control over financial reporting as of December 31, 2018, which is included under Item 15C, below.

C. Attestation Report of the Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by Deloitte Statsautoriseret Revisionspartnerselskab, an independent registered public accounting firm, as stated in their report, which appears in Item 18 on page F-4.

D. Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the period covered by this annual report that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting.

Item 16A *Audit Committee Financial Expert*

Mr. Lars Holtug, an independent director and a member of the Audit Committee, qualifies as an "audit committee financial expert," as defined in Item 16A of Form 20-F and as determined by our board of directors.

Item 16B *Code of Ethics*

We have adopted a code of business conduct and ethics that applies to all of our employees, members of our senior management and members of our board of directors, including those members of our senior management responsible for financial reporting. Our code of ethics is posted on our company website at: http://www.ascendispharma.com. We will disclose any substantive amendments to the code of business conduct and ethics, or any waiver of its provisions, on our website. The reference to our website does not constitute incorporation by reference of the information contained at or available through our website.

Item 16C ***Principal Accountant Fees and Services***

The following table sets forth, for each of the years indicated, the fees billed by our independent public accountants and the percentage of each of the fees out of the total amount billed by the accountants.

	Year ended December 31, 2018		Year ended December 31, 2017	
	EUR'000	%	EUR'000	%
Audit Fees	693	92%	566	100%
Audit-related Fees	—	—	—	—
Tax Fees	—	—	—	—
All Other Fees	62	8%	—	—
Total	755	100%	**566**	**100%**

Audit Fees are defined as the standard audit work that needs to be performed each year to issue opinions on our consolidated financial statements and to issue reports on our local statutory financial statements. Also included are services that can only be provided by our auditor, such as reviews of quarterly financial results, consents and comfort letters and any other audit services required for SEC or other regulatory filings.

Audit Related Fees include those other assurance services provided by the independent auditor but not restricted to those that can only be provided by the auditor signing the audit report.

Tax Fees relate to the aggregated fees for services rendered on tax compliance.

All Other Fees are any additional amounts billed for products and services provided by the principal accountant.

Pre-Approval Policies and Procedures for Non-Audit Services

Our Audit Committee has adopted a policy pursuant to which we will not engage our auditors to perform any non-audit services unless the audit committee pre-approves the service, effective for the period following the completion of our initial public offering.

Item 16D ***Exemptions from the Listing Standards for Audit Committees***

Not applicable.

Item 16E ***Purchases of Equity Securities by the Issuer and Affiliated Purchasers***

None.

Item 16F ***Change in Registrants Certifying Accountant***

None.

Item 16G ***Corporate Governance***

The Sarbanes-Oxley Act of 2002, as well as related rules subsequently implemented by the SEC, requires foreign private issuers, including our company, to comply with various corporate governance practices. In addition, Nasdaq rules provide that foreign private issuers may follow home country practice in lieu of the Nasdaq corporate governance standards, subject to certain exceptions and except to the extent that such exemptions would be contrary to U.S. federal securities laws. In addition to the home country practices described under Item 6.C of this annual report, the home country practices followed by our company in lieu of Nasdaq rules are described below:

- We do not intend to follow Nasdaq's quorum requirements applicable to meetings of shareholders. In accordance with Danish corporate law and generally accepted business practice, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders.
- We do not intend to follow Nasdaq's requirements regarding the provision of proxy statements for general meetings of shareholders. Danish corporate law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in Denmark. We do intend to provide shareholders with an agenda and other relevant documents for the general meeting of shareholders.
- We do not intend to follow Nasdaq's requirements regarding shareholder approval for certain issuances of securities under Nasdaq Rule 5635. Pursuant to Danish corporate law our shareholders have authorized our board of directors to issue securities including in connection with certain events such as the acquisition of shares or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us, rights issues at or below market price, certain private placements and issuance of convertible notes. We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act of 2002, the rules adopted by the SEC and Nasdaq's listing standards. As a Danish company not listed on a regulated market within the EU/EEA, we do not need to comply with the Danish corporate governance principles nor do we need to explain any deviation from these provisions in our Danish statutory annual report.
- We do not intend to follow Nasdaq's requirements regarding shareholder approval for all equity compensation plans. Generally, Nasdaq Rule 5635(c) requires each issuer to obtain shareholder approval of all equity compensation plans (including warrant incentive plans) and material amendments to such plans. However, pursuant to Nasdaq Rule 5615(a)(3), we have elected to follow our home country's practices (in this case, being Danish practices) in lieu of the requirements of Nasdaq Rule 5635(c). Our home country practices do not require us to obtain a shareholders' approval for amendments to our existing warrant incentive program.

Because we are a foreign private issuer, our members of our board of directors, executive board members and senior management are not subject to short-swing profit and insider trading reporting obligations under section 16 of the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act. They will, however, be subject to the obligations to report changes in share ownership under section 13 of the Exchange Act and related SEC rules.

Item 16H *Mine Safety Disclosure*

Not applicable.

PART III

Item 17 *Financial Statements*

See "Item 18 Financial Statements."

Item 18 *Financial Statements*

ASCENDIS PHARMA A/S

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Ascendis Pharma A/S

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Ascendis Pharma A/S and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of profit or loss and other comprehensive income, the consolidated statements of changes in equity, and the consolidated cash flow statements for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated April 3, 2019, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte Statsautoriseret Revisionspartnerselskab

CVR no. 33963556

Copenhagen, Denmark

April 3, 2019

/s/ Henrik Kjelgaard

State-Authorised Public Accountant

/s/ Max Damborg

State-Authorised Public Accountant

We have served as the Company's auditor since 2007.

Deloitte.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Ascendis Pharma A/S

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Ascendis Pharma A/S and subsidiaries (the "Company") as of December 31, 2018, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2018, of the Company and our report dated April 3, 2019, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying management's annual report on internal control over financial reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte Statsautoriseret Revisionspartnerselskab
CVR no. 33963556

Copenhagen, Denmark
April 3, 2019

/s/ Henrik Kjelgaard
State-Authorised Public Accountant

/s/ Max Damborg
State-Authorised Public Accountant

Consolidated Statements of Profit or Loss and Other Comprehensive Income for the Years Ended December 31

	Notes	2018	2017	2016
			(EUR'000)	
Revenue	4, 5	10,581	1,530	4,606
Research and development costs		(140,281)	(99,589)	(66,022)
General and administrative expenses		(25,057)	(13,482)	(11,504)
Operating profit/(loss)		**(154,757)**	**(111,541)**	**(72,920)**
Share of profit/(loss) of associate	12	(321)	—	—
Finance income	7	24,714	923	7,300
Finance expenses	7	(127)	(13,756)	(3,112)
Profit/(loss) before tax		**(130,491)**	**(124,374)**	**(68,732)**
Tax on profit/(loss) for the year	8	394	477	227
Net profit/(loss) for the year		**(130,097)**	**(123,897)**	**(68,505)**
Other comprehensive income/(loss)				
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translating foreign operations		17	65	6
Other comprehensive income/(loss) for the year, net of tax		**17**	**65**	**6**
Total comprehensive income/(loss) for the year, net of tax		**(130,080)**	**(123,832)**	**(68,499)**
Profit/(loss) for the year attributable to owners of the Company		(130,097)	(123,897)	(68,505)
Total comprehensive income/(loss) for the year attributable to owners of the Company		(130,080)	(123,832)	(68,499)
		EUR	EUR	EUR
Basic and diluted earnings/(loss) per share		(3.17)	(3.68)	(2.58)
Number of shares used for calculation (basic and diluted) (1)		41,085,237	33,626,305	26,564,414

(1) A total of 5,611,629 warrants outstanding as of December 31, 2018 (a total of 4,621,154 warrants and 3,691,765 warrants outstanding as of December 31, 2017 and 2016, respectively) can potentially dilute earnings per share in the future but have not been included in the calculation of diluted earnings per share because they are antidilutive for the periods presented.

Consolidated Statements of Financial Position as of December 31,

	Notes	2018	2017
		(EUR'000)	
Assets			
Non-current assets			
Intangible assets	**9**	3,495	3,495
Property, plant and equipment	**10**	4,325	2,557
Investment in associate	**12**	17,083	—
Deposits	**17**	1,158	293
		26,061	**6,345**
Current assets			
Trade receivables	**17**	6	188
Other receivables		1,775	1,410
Prepayments		12,415	6,907
Income taxes receivable	**8**	849	778
Cash and cash equivalents	**17**	277,862	195,351
		292,907	**204,634**
Total assets		**318,968**	**210,979**
Equity and liabilities			
Equity			
Share capital	**13**	5,659	4,967
Distributable equity	**14**	274,391	182,244
Total equity		**280,050**	**187,211**
Current liabilities			
Contract liabilities	**15**	6,902	—
Trade payables	**17**	19,740	17,434
Other payables		12,267	6,334
Income taxes payable		9	—
		38,918	**23,768**
Total liabilities		**38,918**	**23,768**
Total equity and liabilities		**318,968**	**210,979**

Consolidated Statements of Changes in Equity

	Distributable Equity (EUR '000)					
	Share Capital	Share Premium	Foreign Currency Translation Reserve	Share-based Payment Reserve	Accumulated Deficit	Total
Equity at January 1, 2016	**3,374**	**182,085**	**(85)**	**5,763**	**(70,808)**	**120,329**
Loss for the year	—	—	—	—	(68,505)	(68,505)
Other comprehensive loss, net of tax	—	—	6	—	—	6
Total comprehensive income/(loss)	**—**	—	**6**	**—**	**(68,505)**	**(68,499)**
Share-based payment (Note 6)	—	—	—	7,321	—	7,321
Capital increase	980	124,986	—	—	—	125,966
Cost of capital increase	—	(8,504)	—	—	—	(8,504)
Equity at December 31, 2016	**4,354**	**298,567**	**(79)**	**13,084**	**(139,313)**	**176,613**
Loss for the year	—	—	—	—	(123,897)	**(123,897)**
Other comprehensive loss, net of tax	—	—	65	—	—	**65**
Total comprehensive income/(loss)	**—**	—	**65**	**—**	**(123,897)**	**(123,832)**
Share-based payment (Note 6)	—	—	—	9,709	—	**9,709**
Capital increase	613	132,496	—	—	—	**133,109**
Cost of capital increase	—	(8,388)	—	—	—	**(8,388)**
Equity at December 31, 2017	**4,967**	**422,675**	**(14)**	**22,793**	**(263,210)**	**187,211**
Loss for the year	—	—	—	—	(130,097)	**(130,097)**
Other comprehensive loss, net of tax	—	—	17	—	—	**17**
Total comprehensive income/(loss)	**—**	—	**17**	**—**	**(130,097)**	**(130,080)**
Share-based payment (Note 6)	—	—	—	19,652	—	**19,652**
Capital increase	692	215,693	—	—	—	**216,385**
Cost of capital increase	—	(13,118)	—	—	—	**(13,118)**
Equity at December 31, 2018	**5,659**	**625,250**	**3**	**42,445**	**(393,307)**	**280,050**

Consolidated Cash Flow Statements for the year Ended December 31

	2018	2017	2016
		(EUR'000)	
Operating activities			
Net profit/(loss) for the year	**(130,097)**	**(123,897)**	**(68,505)**
Reversal of non-cash consideration regarding revenue	(10,508)	—	—
Reversal of share of profit/(loss) of associate	321	—	—
Reversal of finance income	(24,714)	(923)	(7,300)
Reversal of finance expenses	127	13,756	3,112
Reversal of tax charge	(394)	(477)	(227)
Adjustments for:			
Share-based payment	19,652	9,709	7,321
Depreciation and amortization	880	734	677
Changes in working capital:			
Deposits	(865)	(25)	2
Trade receivables	182	99	777
Other receivables	(365)	(770)	(302)
Prepayments	(5,508)	(4,945)	1,857
Trade payables and other payables	8,262	10,755	4,711
Contract liabilities (deferred income)	—	(94)	(2,978)
Cash flows generated from/(used in) operations	**(143,027)**	**(96,078)**	**(60,855)**
Finance income received	4,020	923	123
Finance expenses paid	(127)	(97)	(5)
Income taxes received / (paid)	332	153	558
Cash flows from/(used in) operating activities	**(138,802)**	**(95,099)**	**(60,179)**
Investing activities			
Acquisition of property, plant and equipment	(2,648)	(941)	(672)
Cash flows used in investing activities	**(2,648)**	**(941)**	**(672)**
Financing activities			
Capital increase	216,385	133,109	125,966
Cost of capital increase	(13,118)	(8,388)	(8,504)
Cash flows from / (used in) financing activities	**203,267**	**124,721**	**117,462**
Increase / (decrease) in cash and cash equivalents	**61,817**	**28,681**	**56,611**
Cash and cash equivalents at January 1	195,351	180,329	119,649
Effect of exchange rate changes on balances held in foreign currencies	20,694	(13,659)	4,069
Cash and cash equivalents at December 31	**277,862**	**195,351**	**180,329**
Restricted cash included in cash and cash equivalents	**5,566**	**63**	**—**

Note 1—General Information

Ascendis Pharma A/S, together with its subsidiaries, is a clinical stage biopharmaceutical company applying its innovative TransCon technologies to build a leading, fully integrated rare disease company. Ascendis Pharma A/S was incorporated in 2006 and is headquartered in Hellerup, Denmark. Unless the context otherwise requires, references to the "Company," "we," "us" and "our" refer to Ascendis Pharma A/S and its subsidiaries.

The address of the Company's registered office is Tuborg Boulevard 12, DK-2900 Hellerup, Denmark. The Company's registration number in Denmark is 29918791.

On February 2, 2015, the Company completed an initial public offering, or IPO, which resulted in the listing of American Depositary Shares, or ADSs, representing the Company's ordinary shares, under the symbol "ASND" in the United States on The Nasdaq Global Select Market.

The Company's Board of Directors approved these consolidated financial statements on April 3, 2019.

Note 2—Summary of Significant Accounting Policies

Basis of Preparation

The consolidated financial statements are prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, and as adopted by the European Union, or EU.

The accounting policies applied when preparing the consolidated financial statements are described in detail below and are applied for all entities. Unless otherwise stated under the section "Changes in Accounting Policies and Disclosures" below, these policies have been applied consistently to all years presented. Significant accounting estimates used when exercising the accounting policies are described in Note 3.

Our consolidated financial statements have been prepared under the historical cost convention, apart from certain financial instruments that are measured at fair value at initial recognition.

Changes in Accounting Policies and Disclosures

New and Amended Standards and Interpretations

As of January 1, 2018, the Company has adopted IFRS 9, "Financial Instruments", which introduces a new impairment model for financial assets measured at amortized cost based on an expected credit loss model, which currently applies to the Company's bank deposits, trade receivables and deposits. The implementation of the impairment model under IFRS 9 had no impact on the consolidated financial statements.

At December 31, 2017, €17.4 million of trade payables and €6.3 million of other payables were combined and presented as a single amount of trade payables and other payables under current liabilities in the consolidated statements of financial position. In connection with adoption of IFRS 9, and in order to separate financial liabilities from other payables, we have from December 31, 2018, presented other payables separately from trade payables in the consolidated statements of financial position. Comparative figures have been reclassified to reflect the change in presentation. The adoption of IFRS 9 had no other impact on the consolidated financial statements.

Further, the Company has adopted IFRS 15, "Revenue from Contracts with Customers", which establishes a single, comprehensive framework for revenue recognition, based on a five-step model, which applies to the Company's licensing agreements with multiple activities. IFRS 15 was adopted as of January 1, 2018 using the "retrospective method with the cumulative effect of initially applying this standard recognized at the date of the initial application". The adoption of IFRS 15 had no impact on the consolidated financial statements.

Going Concern

The Company's Board of Directors has, at the time of approving the consolidated financial statements, a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Thus, we continue to adopt the going concern basis of accounting in preparing the financial statements.

Recognition and Measurement

Assets are recognized in the consolidated statements of financial position when it is probable, as a result of a prior event, that future economic benefits will flow to us and the value of the asset can be measured reliably.

Liabilities are recognized in the consolidated statements of financial position when we have a legal or constructive obligation as a result of a prior event, and it is probable that future economic benefits will flow from us and the value of the liability can be measured reliably.

On initial recognition, assets and liabilities are measured at cost or at fair value, depending on the classification of the items. Measurement subsequent to initial recognition is affected as described below for each financial statement item. Anticipated risks and losses that arise before the time of presentation of the consolidated financial statements and that confirm or invalidate affairs and conditions existing at the consolidated statements of financial position date are considered at the time of recognition and measurement.

Income is recognized in the consolidated statements of profit or loss when earned, whereas costs are recognized by the amounts attributable to the financial year.

Basis of Consolidation

The consolidated financial statements include our parent company, Ascendis Pharma A/S, and all enterprises over which the parent company has control. We control an enterprise when we are exposed to, or have rights to, variable returns from our involvement with the enterprise and have the ability to control those returns through our power over the entity. Accordingly, the consolidated financial statements include Ascendis Pharma A/S and the subsidiaries listed in Note 11.

Consolidation Principles

The consolidated financial statements comprise the Company, and its subsidiaries at December 31, 2018. Subsidiaries, which are enterprises where we have control at the balance sheet date, are fully consolidated from the date upon which control is transferred to us. They are deconsolidated from the date control ceases.

We re-assess whether or not the Company controls an enterprise if facts and circumstances indicate that there are changes to one or more of the three elements of control, respectively:

- The contractual arrangement(s) with the other vote holders of the enterprise
- The Group's voting rights and potential voting rights
- Rights arising from other contractual arrangements

All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between our group enterprises are eliminated in full on consolidation.

Subsidiaries and our associate apply accounting policies in line with the Company's accounting policies. When necessary, adjustments are made to bring the entities' accounting policies in line with those of the Company.

An associate is an entity over which we have significant influence over financial and operational decisions but where we have neither control nor joint control. The Company's associate is accounted for using the equity method. Under the equity method, the associate is initially recognized at cost. Thereafter, the carrying amount of the investment is adjusted to recognize changes in the Company's share of net assets of the associate since the acquisition date.

The consolidated statements of profit or loss includes the Company's share of result after tax and non-controlling interests of the associate. Transactions between the associate and the Company are eliminated proportionally according to our interest in the associate. Unrealized gains and losses resulting from transactions between the Group and its associate is eliminated to the extent of the interest in the associate.

After application of the equity method, we determine whether it is necessary to recognize an impairment loss related to the associate. Accordingly, at each reporting date, we determine whether there is objective evidence that the associate is impaired. If there is such evidence, we calculate the amount of impairment as the difference between the recoverable amount of the associate and its carrying value. Any impairment loss is recognized within share of profit/(loss) of associate in the consolidated statements of profit or loss.

Foreign Currency

Functional and Presentation Currency

Items included in the consolidated financial statements are measured using the functional currency of each Group entity. Functional currency is the currency of the primary economic environment in which the entity operates. The consolidated financial statements are presented in Euro (EUR), which is also the functional currency of the parent company.

Translation of Transactions and Balances

On initial recognition, transactions in currencies other than the individual entity's functional currency are translated applying the exchange rate in effect at the date of the transaction. Receivables, payables and other monetary items denominated in foreign currencies that have not been settled at the balance sheet date are translated using the exchange rate in effect at the balance sheet date.

Exchange rate differences that arise between the rate at the transaction date and the rate in effect at the payment date, or the rate at the balance sheet date, are recognized in profit or loss as financial income or financial expenses. Property, plant and equipment, intangible assets and other non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions.

Currency Translation of Group Enterprises

When subsidiaries or associates that present their financial statements in a functional currency other than EUR are recognized in the consolidated financial statements, their statements of profit or loss are translated at average exchange rates. Balance sheet items are translated using the exchange rates at the balance sheet date. Exchange rate differences arising from translation of foreign entities' balance sheet items at the beginning of the year to the balance sheet date exchange rates as well as from translation of statements of profit or loss from average rates to the exchange rates at the balance sheet date are recognized in other comprehensive income. Similarly, exchange rate differences arising from changes that have been made directly in a foreign subsidiary's equity are recognized in other comprehensive income.

Business Combinations

Newly acquired or newly established subsidiaries are recognized in the consolidated financial statements from the time of acquiring or establishing such enterprises. Time of acquisition is the date on which control of the enterprise is actually acquired.

When acquiring new enterprises over which we obtain control, the acquisition method is applied. Under this method, we identify assets, liabilities and contingent liabilities of these enterprises and measure them at fair value at the acquisition date. Restructuring costs are only recognized in the pre-acquisition balance sheet if they constitute a liability of the acquired enterprise. Allowance is made for the tax effect of the adjustments made.

The acquisition price for an enterprise consists of the fair value of the consideration paid for the acquired enterprise. Costs that are attributable to the acquisition of the enterprise are recognized in the consolidated statement of profit or loss when incurred.

The excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the identifiable net assets acquired are all recorded as goodwill.

Goodwill is subject to annual impairment test. Impairment is calculated as the difference between the recoverable amount of the cash-generating unit that the goodwill relates to, and it's carrying amount. Any impairment loss is recognized in the consolidated statement of profit or loss in a separate line item.

Revenue

Our revenue is primarily generated from collaboration- and license agreements. Further, we also generate revenue from development services under development and commercialization agreements. Additionally, revenue is generated from feasibility studies for potential partners to evaluate if our TransCon technologies enables certain advantages for their product candidates of interest. Such feasibility studies are often structured as short-term agreements with fixed fees for the work that we perform.

With reference to "Changes to accounting policies and disclosures", the Company has adopted IFRS 15, "Revenue from Contracts with Customers", effective from January 1, 2018. Thus, until December 31, 2017 revenue was recognized when it was probable that future economic benefits would flow to us and these benefits could be measured reliably. Further, revenue recognition required that all significant risks and rewards of ownership of the goods or services included in the transaction had been transferred to the buyer, and that we retained neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods or services sold.

From January 1, 2018, upon adoption of IFRS 15, when we enter into contract with customers, we assess the goods and/or services promised in the contract and identify distinct performance obligations. A promise in the agreement is considered a distinct performance obligation if both of the following criteria are met:

- the customer can benefit from the goods or service either on its own or together with other resources that are readily available to the customer (i.e. the goods or service is capable of being distinct); and
- the entity's promise to transfer the goods or service to the customer is separately identifiable from other promises in the contract (i.e. the promise to transfer the goods or service is distinct within the context of the contract).

Under collaboration-, license, and other agreements that contain multiple promises to the customer, the promises are identified and accounted for as separate performance obligations, if these are distinct. If promises are not distinct, we combine those goods or services with other promised goods or services until we identify a bundle of goods or services that is distinct.

The transaction price in the contract is measured at fair value and reflects the consideration we expect to be entitled to in exchange for those goods or services. In the transaction price, variable consideration including milestone payments, is only included to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The transaction price is allocated to each performance obligation according to their stand-alone selling prices and is recognized when control of the goods or services are transferred to the customer either, over time or at a point in time.

Revenue is stated net of value added tax, duties, etc. collected on behalf of a third party, and discounts. Usually the payment terms are within 1-2 months. We have no payment terms exceeding 12 months, and thus transaction prices are not adjusted for financing components.

The transition to IFRS 15 had no impact on recognition and measurement of revenue.

Research and Development Costs

Our research and development costs consist primarily of manufacturing costs, preclinical and clinical study costs, salaries and other personnel costs including pension and share-based payment, the cost of facilities, the cost of obtaining and maintaining our intellectual property portfolio, and the depreciation of assets used in research and development activities.

Research costs comprise costs incurred at the early stages of the drug development cycle from the initial drug discovery and are recognized in the consolidated statement of profit or loss when incurred.

A development project involves a single product candidate undergoing a series of studies to illustrate its safety profile and effect on human beings prior to obtaining the necessary approval from the appropriate authorities. Due to the risk related to the development of pharmaceutical products, we cannot estimate the future economic benefits associated with individual development projects with sufficient certainty until the development project has been finalized and the necessary market approval of the final product has been obtained. As a consequence, all development costs are recognized in the consolidated statement of profit or loss in the period to which they relate. Development costs also comprise manufacturing costs related to validation batches, or process performance qualification batches, on late-stage development projects.

General and Administrative Expenses

General and administrative expenses comprise salaries and other personnel costs including pension and share-based payment, office supplies, cost of facilities, and depreciation and amortization related to administrative activities.

General and administrative expenses are recognized in the consolidated statement of profit or loss in the period to which they relate.

Share-based Incentive Programs

Share-based incentive programs under which board members, employees and external consultants have the option to purchase shares in Ascendis Pharma A/S (equity-settled share-based payment arrangements) are measured at the equity instrument's fair value at the grant date.

The cost of equity-settled transactions is determined by the fair value at the date of grant using the Black-Scholes valuation model. The cost is recognized together with a corresponding increase in equity over the period in which the performance and/or service conditions are fulfilled, the vesting period. The fair value determined at the grant date of the equity-settled share-based payment is expensed on a straight-line basis over the vesting period for each tranche, based on our best estimate of the number of equity instruments that will ultimately vest. No expense is recognized for grants that do not ultimately vest.

Where an equity-settled grant is cancelled, it is treated as if it vested on the date of the cancellation, and any expense not yet recognized for the grant is recognized immediately. This includes any grant where non-vesting conditions within the control of either the entity or the employee are not met.

Where the terms and conditions for an equity-settled grant is modified, we recognize as minimum the services measured at the grant date fair value over the vesting period. Additionally, we re-measure the unvested grants at the date of modification and recognize any increase in the total fair value over the vesting period.

If a new grant is substituted for the cancelled grant and designated as a replacement grant on the date that it is granted, the cancelled and new grants are treated as if they were a modification of the original grant, as described in the previous paragraph.

Any social security contributions payable in connection with the grant or exercise of the warrants are recognized as incurred.

The assumptions used for estimating the fair value of share-based payment transactions are disclosed in Note 6.

Finance Income and Expenses

Finance income and expenses comprise interest income and expenses and realized and unrealized exchange rate gains and losses on transactions denominated in foreign currencies.

Interest income and interest expenses are stated on an accrual basis using the principal and the effective interest rate. The effective interest rate is the discount rate that is used to discount expected future payments related to the financial asset or the financial liability in order for the present value of such asset or liability to match their carrying amount.

Income Taxes

Tax for the year, which consists of current tax for the year and changes in deferred tax, is recognized in the consolidated statement of profit or loss by the portion attributable to the profit or loss for the year and recognized directly in equity or other comprehensive income by the portion attributable to entries directly in equity and in other comprehensive income. The current tax payable or receivable is recognized in the balance sheet, stated as tax computed on this year's taxable income, adjusted for prepaid tax.

When computing the current tax for the year, the tax rates and tax rules enacted or substantially enacted at the balance sheet date are used. Current tax payable is based on taxable profit or loss for the year. Taxable profit or loss differs from net profit or loss as reported in the consolidated statements of profit or loss because it excludes items of income or expense that are taxable or deductible in prior or future years. It also further excludes items that are never taxable or deductible.

Deferred tax is recognized according to the balance sheet liability method of all temporary differences between carrying amounts and tax-based values of assets and liabilities, apart from deferred tax on all temporary differences occurring on initial recognition of goodwill or on initial recognition of a transaction which is not a business combination, and for which the temporary difference found at the time of initial recognition neither affects net profit or loss nor taxable income.

Deferred tax liabilities are recognized on all temporary differences related to investments in our subsidiaries, unless we are able to control when the deferred tax is realized, and it is probable that the deferred tax will not become due and payable as current tax in the foreseeable future.

Deferred tax is calculated based on the planned use of each asset and the settlement of each liability, respectively.

Deferred tax is measured using the tax rates and tax rules in the relevant countries that, based on acts in force or acts in reality in force at the balance sheet date, are expected to apply when the deferred tax is expected to crystallize as current tax. Changes in deferred tax resulting from changed tax rates or tax rules are recognized in the consolidated statement of profit or loss unless the deferred tax is attributable to transactions previously recognized directly in equity or other comprehensive income. In the latter case, such changes are also recognized in equity or other comprehensive income.

Deferred tax assets, including the tax base of tax loss carry forwards, are recognized in the balance sheet at their estimated realizable value, either as a set-off against deferred tax liabilities or as net tax assets for offset against future positive taxable income. At every balance sheet date, it is assessed whether sufficient taxable income is likely to arise in the future for the deferred tax asset to be used.

Intangible Assets

Goodwill

Goodwill is initially measured at cost, being the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests over the net identifiable assets acquired and liabilities assumed. After initial recognition, goodwill is measured at cost less any accumulated impairment losses. Goodwill is not amortized but is subject to impairment testing at least on a yearly basis. For the purpose of impairment testing, goodwill acquired in a business combination is allocated to each of the cash-generating units, or group of cash-generating units, that are expected to benefit from the synergies of the combination. Each cash-generating unit or group of cash generating units to which goodwill is allocated represent the lowest level within the Company at which the goodwill is monitored for internal management purposes. Goodwill is monitored at the consolidated level.

Property, Plant and Equipment

Property, plant and equipment is measured at cost less accumulated depreciation and impairment losses. Cost comprises the acquisition price, costs directly attributable to the acquisition and preparation costs of the asset until the time when it is ready to be put into operation.

Subsequent costs are included in the carrying amount of the asset or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the assets will flow to us and the costs of the items can be measured reliably. All repair and maintenance costs are charged to the consolidated statement of profit or loss during the financial periods in which they are incurred.

Plant and equipment acquired for research and development activities, which are expected to be used for research and development activities for more than one year, are capitalized and depreciated over the estimated useful life as research and development costs.

If the acquisition or use of the asset involves an obligation to incur costs of decommissioning or restoration of the asset, the estimated related costs are recognized as a provision and as part of the relevant asset's cost, respectively.

The basis for depreciation is cost less estimated residual value. The residual value is the estimated amount that would be earned if selling the asset today net of selling costs, assuming that the asset is of an age and a condition that is expected after the end of its useful life. The cost of a combined asset is divided into smaller components, with such components depreciated individually if their useful lives vary.

Depreciation commences when the asset is available for use, which is when it is in the location and condition necessary for it to be capable of operating in the manner we intend.

Depreciation is calculated on a straight-line basis from the following assessment of an asset's expected useful life:

Process plant and machinery	5 - 10 years
Other fixtures and fittings, tools and equipment	3 - 5 years
Leasehold improvements	3 - 5 years

The useful life for plant and equipment used in specific development activities, reflects the estimated time of the relevant development project.

Depreciation methods, useful lives and residual amounts are re-assessed at least annually.

Property, plant and equipment are written down to the lower of recoverable amount and carrying amount, as described in the "Impairment" section below.

Depreciation, impairment losses and gains and losses on disposal of property, plant and equipment are recognized in the consolidated statement of profit or loss as research and development costs or as general and administrative expenses, as appropriate.

Impairment

Property, plant and equipment and finite-lived intangible assets are reviewed for impairment whenever events or circumstances indicate that the carrying amount may not be recoverable. The recoverable amount of goodwill is estimated annually irrespective of any recorded indications of impairment.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purpose of assessing impairment, assets are grouped at the lowest levels for which there are largely independent cash inflows, or cash-generating units, which for goodwill represent the lowest level within the enterprise at which the goodwill is monitored for internal management purposes. Prior impairments of non-financial assets, other than goodwill, are reviewed for possible reversal at each reporting date.

Receivables

Receivables comprise deposits, trade receivables, and other receivables, which are separately presented in the consolidated statements of financial position.

With reference to "Changes to accounting policies and disclosures", the Company has adopted IFRS 9, "Financial Instruments", effective as of January 1, 2018. Thus, until December 31, 2017, deposits and trade receivables were classified as loans and receivables, constituting financial assets with fixed or determinable payments. Receivables were initially recognized at their fair value, and subsequently measured at amortized cost.

From January 1, 2018, receivables (excluding receivables related to VAT and other indirect tax receivables) are classified as financial assets at amortized cost, as these are held to collect contractual cash flows and thus give rise to cash flows representing solely payments of principal and interest. Trade receivables are initially recognized at their transaction price and subsequently measured at amortized cost. Deposits are initially measured at their fair value and subsequently measured at amortized cost.

Other receivables comprise VAT and other indirect tax receivables, and thus not classified as financial assets, are measured at cost less impairment.

The carrying amount of receivables usually equals their nominal value less provision for impairments.

Prepayments

Prepayments comprise costs relating to a future financial period. Prepayments are measured at cost.

Cash and Cash Equivalents

Cash and cash equivalents comprise cash and demand deposits with financial institutions. Cash and cash equivalents are measured at amortized cost.

Allowance for Expected Credit Losses on Financial Assets

Financial assets comprise receivables (excluding receivables relating to VAT and other indirect tax receivables) and cash and cash equivalents.

In connection with adoption of IFRS 9, the Company has implemented a new impairment model for financial assets measured at amortized cost based on an expected credit loss model. Until December 31, 2017, provision for bad debts on financial assets was determined on the basis of an individual assessment of each receivable and recognized using an allowance account. From January 1, 2018 provision for bad debts is determined on the basis of a forward-looking expected credit loss (ECL") model. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and the cash flows that we expect to receive, discounted at an approximation of the original effective interest rate.

For receivables, we will apply a simplified approach in calculating ECLs. Therefore, we will not track changes in credit risk, but instead we will assess a loss allowance based on lifetime ECL at each reporting date. Lifetime ECLs will be assessed on historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

For cash and cash equivalents, ECLs are assessed in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are assessed for credit losses that result from default events that are possible within the next 12-months ("12-month ECL"). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default ("lifetime ECL").

Shareholders' Equity

The share capital comprises the nominal amount of the parent company's ordinary shares, each at a nominal value of DKK 1, or approximately €0.13. All shares are fully paid.

Share premium reserve comprises the amounts received, attributable to shareholders' equity, in excess of the nominal amount of the shares issued at the parent company's capital increases, reduced by any expenses directly attributable to the capital increases.

Foreign currency translation reserve includes exchange rate adjustments relating to the translation of the results and net assets of our foreign operations from their functional currencies to our presentation currency. The accumulated reserve of a foreign operation is recognized in the consolidated statement of profit or loss at the time we lose control, and thus cease to consolidate such foreign operation. The foreign currency translation reserve is an unrestricted reserve that is available to be distributed as dividends to the Company's shareholders.

Reserve for share-based payment represents the corresponding entries to the share-based payment recognized in the consolidated statement of profit or loss, arising from our warrant programs.

Retained earnings or accumulated deficit represents the accumulated profits or losses from the Company's operations. A positive reserve is available to be distributed as dividends to the Company's shareholders.

Leases

Leases of property, plant and equipment, where we have substantially all of the risks and rewards of ownership, are classified as finance leases. Other leases are classified as operating leases.

No finance leases were in place at December 31, 2018 or December 31, 2017. Lease payments on operating leases are recognized on a straight-line basis in the consolidated statement of profit or loss over the term of the lease.

Total commitments under operating leases is disclosed in note 16.

Trade Payables

Trade payables including accrued expenses are measured at amortized cost applying the effective interest method to the effect that the difference between proceeds and nominal amount is recognized in the consolidated statement of profit or loss as a financial expense over the term of the liability.

Other Payables

Other payables comprise payables to public authorities, and short-term employee benefits payable within one year. Other payables are measured at their net-realizable values.

Contract Liabilities

Contract liabilities comprise deferred income from collaboration agreements and license agreements, where consideration received do not match the individual deliverables with respect to amount and satisfied performance obligations. Deferred income typically arises from up-front payments under our collaboration- and license agreements, relating to license grants or up-front funding of development activities. If we are participating in continued development of product candidates, up-front payments are recognized as deferred income and recognized as revenue over the anticipated period in which we are involved in the development activities. Deferred income is measured at the fair value of the income received.

Deferred income is recognized as revenue in the consolidated statement of profit or loss when the relevant performance obligation, to which the deferred revenue relates, is satisfied.

Cash Flow Statement

The cash flow statement shows cash flows from operating, investing and financing activities as well as cash and cash equivalents at the beginning and the end of the financial year.

Cash flows from operating activities are presented using the indirect method and calculated as the profit or loss adjusted for non-cash items, working capital changes as well as financial income, financial expenses and income taxes paid.

Cash flows from investing activities comprise payments in connection with acquisitions, development, improvement and sale, etc. of intangible assets, property, plant and equipment, and group enterprises.

Cash flows from financing activities comprise changes in the share capital of Ascendis Pharma A/S and related costs.

The effect of exchange rate changes on cash and cash equivalents held or due in a foreign currency is presented separately from cash flows from operating, investing and financing activities.

Cash flows in currencies other than the functional currency are recognized in the cash flow statement, using the average exchange rates.

Cash and cash equivalents comprise cash at hand and deposits with financial institutions.

Any restricted cash included in the balance of cash and cash equivalents is presented as an additional disclosure in the cash flow statement.

Segment Reporting

We are managed and operated as one operating and reportable segment. No separate operating segments or reportable segments have been identified in relation to product candidates or geographical markets. Accordingly, except for entity wide disclosures, we do not disclose segment information on business segments or geographical markets.

Basic EPS

Basic Earnings per Share, or EPS, is calculated as the consolidated net income or loss from continuing operations for the period divided by the weighted average number of ordinary shares outstanding.

Diluted EPS

Diluted earnings per share is calculated as the consolidated net income or loss from continuing operations for the period divided by the weighted average number of ordinary shares outstanding adjusted for the dilutive effect of share equivalents. If the consolidated statement of profit or loss shows a net loss, no adjustment is made for the dilutive effect, as such effect would be anti-dilutive.

New International Financial Reporting Standards Not Yet Effective

The IASB has issued, and the European Union has adopted, a number of new or amended standards, which have not yet become effective. Therefore, these new standards have not been incorporated in these consolidated financial statements. Our financial reporting is expected to be affected by such new or improved standards to the extent described below.

- In January 2016, the IASB issued IFRS 16 “Leases”. The standard was endorsed by the EU in 2017 and will be effective for annual periods beginning on or after January 1, 2019 and replaces the current IAS 17 “Leases”. IFRS 16 requires, with a few exceptions, lessees to recognize assets (“right-of-use assets”) and liabilities for most leases. Accordingly, lease payments under contracts, currently classified as operating leases, will be recognized over the non-cancellable lease period as depreciation included in research and development costs, and general administrative expenses, respectively, and as interest expenses included in finance expenses. Currently, lease payments under operating leases are recognized as research and development costs, and general administrative expenses, respectively.

We will implement IFRS 16, by applying the modified retrospective approach. Accordingly, no comparative information will be restated, and the cumulative impact from implementing the standard will be recognized through retained earnings in the opening balance at January 1, 2019. The lease liability and corresponding lease asset will be measured at the present value of the remaining lease payments, discounted using an estimated incremental borrowing rate at January 1, 2019.

In the consolidated statement of financial position at January 1, 2019, we will recognize a right-of-use asset of €18.0 million, which include prepaid leases at December 31, 2018, and a lease liability of €17.4 million. Additionally, since lease payments will be classified as payments and interest on lease liabilities, the consolidated statement of profit or loss for 2019 will be impacted, from the leases in effect at January 1, 2019, with an increase in operating profit of €349 thousand, and an increase of financial expenses of €492 thousand. Accordingly, the net impact on the consolidated statement of profit or loss for 2019 from implementing IFRS 16 is a net loss of €143 thousand. Leases in effect at January 1, 2019, will impact cash outflow from financing activities for 2019 with €4.3 million, with a corresponding increase in cash flows from operating activities.

Note 3—Critical Accounting Judgments and Key Sources of Estimation Uncertainty

In the application of our accounting policies, we are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

Critical Judgments in Applying Accounting Policies

The following are the critical judgments, apart from those involving estimates, see below, made in the process of applying our accounting policies and that have the most significant effect on the amounts recognized in our consolidated financial statements.

Revenue Recognition

We evaluate all our revenue generating transactions to ensure recognition in accordance with IFRS. Revenue is primarily generated from collaboration- and license agreements, which typically involve multiple promises, and thus require significant judgments by us on certain areas including:

- Determining whether the promises in the agreements are distinct performance obligations;
- Identifying and constraining variable consideration in the transaction price including milestone payments;
- Allocating transaction price to identified performance obligations based on their relative stand-alone selling prices; and
- Determining whether performance obligations are satisfied over time, or at a point in time.

Critical judgments relating to revenue recognition are described below.

Collaboration Agreements

Identifying Performance Obligations

Our two collaboration agreements in place were entered in 2010 and 2013, respectively. The agreements include grant of licenses and contemplate our involvement in the ongoing research and development of our partnered product candidates.

At the time the collaboration agreements were entered, the product candidates were early-stage development projects, where the partnered development activities were considered single performance obligations. Accordingly, up-front fees have been recognized as revenue over time based on our continued involvement in development activities.

License Agreements

The judgments that significantly affect the determination of the amount and timing of revenue from contracts with customers relates to three license agreements, which were entered into in 2018.

Identifying Performance Obligations and Allocating Transaction Price

The three license agreements grant the licensee exclusive rights to develop, manufacture, and commercialize the patented product candidates in Greater China (the "Territory"), including the right to grant sub-licenses to third parties. In addition to the licenses, we will deliver development services and provide clinical supply material to be used in clinical trials within the Territory.

In determination of the performance obligations under the license agreements, we have considered the stand-alone values of the promises in the contracts, and our responsibility in the future development activities including bringing the licensed products to market in the Territory.

While licensed product candidates are all in phase 1 or later, we have concluded that the licensee can benefit from each promise in the contract either on their own or together with readily available resources. Thus, each of the license agreements comprise following distinct performance obligations, licenses, development services, and clinical trial supplies, respectively.

Classification of Licenses as "Right-to-Use" or "Right-to-Access"

We have considered whether we are obligated or expected to perform research and development activities that significantly affect the licensee's ability to benefit from product candidates. If we are contractually obligated, or if we determine that we are expected to perform research and development activities affecting the stand-alone functionality of the product candidate, the license is classified as "right-to-access". Other licenses are classified as "right-to-use".

While licensed products are patented drug formulas, our future activities do not affect their stand-alone functionalities. Accordingly, all three licenses been classified as "right-to-use", with revenue recognized at the point in time, where licensee is granted access to the intellectual property.

Share-Based Payment

IFRS 2, "Share-Based Payment" requires an entity to reflect in its profit or loss and financial position the effects of share-based payment transactions, including expenses associated with transactions in which share options are granted to employees. We have granted warrants to employees, consultants and board members under three different programs.

We use the Black-Scholes option-pricing model to value the warrants granted and critical judgments need to be exercised in determining the appropriate input to the valuation model as well as to determine the appropriate way of recognizing the expenses under IFRS 2.

Warrants granted under our warrant programs vest on a monthly basis over periods of up to 48 months. Due to the graded vesting, the related expenses are recognized on an accelerated basis; i.e. each tranche of a warrant grant is treated separately for expense recognition purposes. Accordingly, the expenses related to each warrant grant is treated in up to 48 tranches, all being recognized over the vesting period.

See Note 6 for additional details on our warrant programs and recognition of expenses under IFRS 2.

Internally Generated Intangible Assets

IAS 38, “Intangible Assets” prescribes that intangible assets arising from development projects must be recognized in the balance sheet if the criteria for capitalization are met. That means (1) that the development project is clearly defined and identifiable; (2) that technological feasibility, adequate resources to complete and a market for the product or an internal use of the project can be documented; (3) that the expenditure attributable to the development project can be measured reliably; and (4) that we have the intent to produce and market the product or use it internally.

Such an intangible asset shall be recognized if it can be documented that the future income from the development project will exceed the aggregate cost of development, production, sale and administration of the product.

Due to the risk associated with drug development, future income from development projects cannot be determined with sufficient certainty until the development activities have been completed and the necessary marketing approvals have been obtained. Accordingly, we do not recognize internally generated intangible assets at this time.

Joint Arrangements / Collaboration Agreements

Collaboration agreements within our industry are often structured so that each party contributes its respective skills in the various phases of a development project. No joint control exists for such collaborations and the parties do not have any financial obligations on behalf of each other. Accordingly, neither of our collaborations nor license agreements are considered to be joint arrangements as defined in IFRS 11, “Joint Arrangements”.

Investment in Associate

On initial recognition of investments, we assess whether we have power over the enterprise. An associate is an enterprise where we have neither control or joint control, but where we have significant influence over financial and operational decisions based on judgment of the following factors:

- the contractual arrangement(s) with the other vote holders of the investee
- board representation
- rights arising from other contractual arrangements
- the Company’s voting rights and rights over protective decisions.

We have analyzed the structure of our investment in VISEN Pharmaceuticals and concluded that the enterprise is classified as an associate as defined in IAS 28 “Investments in Associates and Joint Ventures”.

Key Sources of Estimation Uncertainty

The following are the key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, that have a significant risk of causing a material adjustment to the carrying amount of assets and liabilities within the next financial year.

Revenue Recognition—Allocation of Transaction Price to Performance Obligations

Transaction price for license agreements comprises up-front, non-refundable, non-cash consideration. Additionally, the agreements comprise separate remuneration for clinical supplies and development services, which approximate their stand-alone-selling prices.

For two license agreements, entered in 2018, we have allocated up-front considerations to licenses and development services, respectively. While no active market exists for the licenses, we have determined the stand-alone value of the licenses according to an approximate market approach based on readily available information, which includes estimation uncertainties.

Impairment of Goodwill

Determining whether goodwill is impaired requires an estimation of the recoverable amount, being the higher of fair value less costs of disposal or value in use, of the cash-generating units to which goodwill has been allocated. The Company is determined to be a single cash-generating unit. Accordingly, the recoverable amount is determined based on an estimation of the Company's fair value less costs of disposal. We have determined the fair value of goodwill after taking into account the market value of our ADSs representing the enterprise value of the group enterprise as of the balance sheet date. No impairment loss has been recognized in 2018, 2017 or 2016. The carrying amount of goodwill at December 31, 2018 and 2017 was €3.5 million. See note 9 for further details.

Recognition of Accruals for Manufacturing and Clinical Trial Activities

Payment terms for contractual work related to development, manufacturing and clinical trial activities do not necessarily reflect the stage of completion of the individual projects and activities. Determination of the stage of completion for ongoing activities includes estimation uncertainties as future efforts to complete the specific activity may be difficult to predict. We have reviewed all significant ongoing activities at the balance sheet date to determine the stage of completion compared to the invoices received and recognized accruals for any additional costs.

Useful Lives of Property, Plant and Equipment

We review the estimated useful lives of property, plant and equipment at the end of each reporting period. We have concluded that the useful lives applied for 2018, 2017 and 2016 are appropriate.

Except for the above areas, assumptions and estimates are not considered to be critical to the consolidated financial statements

Note 4—Revenue

Revenue has been recognized in the consolidated statements of profit or loss with the following amounts:

	2018	2017	2016
		(EUR'000)	
Revenue from the rendering of services (recognized over time)	1,215	1,530	1,628
"Right-to-access" licenses (recognized over time)	—	—	2,978
"Right-to-use" licenses (recognized at a point in time)	9,366	—	—
Total revenue	**10,581**	**1,530**	**4,606**

	2018	2017	2016
		(EUR'000)	
Revenue from external customers (geographical)			
North America	10,581	1,530	4,606
Total revenue	**10,581**	**1,530**	**4,606**

Note 5—Segment Information

We are managed and operated as one business unit. No separate business areas or separate business units have been identified in relation to product candidates or geographical markets. Accordingly, except for entity wide disclosures, we do not disclose information on business segments or geographical markets.

Geographical information on revenue is included in Note 4, and the Company's non-current assets are primarily located in our country of domicile, Denmark.

In the consolidated financial statements for 2018, a single customer (our associate) accounts for more than 10% of total revenue. For elaborating details, please refer to Note 12. The revenue from single customers was €10.5 million, €1.5 million, and €4.6 million for the financial years ended December 31, 2018, 2017, and 2016, respectively.

Note 6—Staff Cost

	2018	2017	2016
		(EUR'000)	
Wages and salaries	29,418	19,918	15,288
Share-based payment	19,652	9,709	7,321
Pensions (defined contribution plans)	444	324	49
Social security costs	1,793	1,156	913
Total staff costs	**51,307**	**31,107**	**23,571**
Average number of employees	**167**	**121**	**92**

Staff costs are recognized in the consolidated statement of profit or loss as follows:

	2018	2017	2016
		(EUR'000)	
Research and development costs	34,146	21,845	15,829
General and administrative expenses	17,161	9,262	7,742
Total staff costs	**51,307**	**31,107**	**23,571**

Key Management Personnel includes our Board of Directors (7 persons; 2017: 8 persons) and Executive Board (2 persons; 2017: 2 persons).

Compensation to Key Management Personnel comprises salaries, participation in annual bonus schemes, and share-based compensation. Share-based compensation is elaborated in further details in the section "Share-based payment".

Compensation to Key Management Personnel included above is summarized below:

	2018	2017 (EUR'000)	2016
Compensation to Key Management Personnel			
Wages and salaries	1,809	1,731	1,449
Share-based payment	5,112	3,576	2,548
Pensions (defined contribution plans)	—	—	—
Social security costs	152	70	72
Total Compensation to Key Management Personnel	**7,073**	**5,377**	**4,069**

Out of the total compensation to key management personnel, €1,851 thousand (2017: €1,467 thousand, 2016: €1,187 thousand) related to the Board of Directors, and €5,222 thousand (2017: €3,910 thousand, 2016: €2,882 thousand) related to the Executive Board. Out of the share-based payment to key management personnel, under the warrant programs described below, €1,607 thousand (2017: €1,202 thousand, 2016: €938 thousand) related to the Board of Directors, and €3,505 thousand (2017: €2,374 thousand, 2016: €1,610 thousand) related to the Executive Board.

Share-based payment

Ascendis Pharma A/S has established warrant programs, equity-settled share-based payment transactions, as an incentive for all of our employees, members of our Board of Directors and select external consultants.

Warrants are granted by the Board of Directors in accordance with authorizations given to it by the shareholders of Ascendis Pharma A/S. As of December 31, 2018, 8,078,187 warrants had been granted, of which 19,580 warrants have been cancelled, 2,212,528 warrants have been exercised, 2,168 warrants have expired without being exercised, and 232,282 warrants have been forfeited. As of December 31, 2018, our Board of Directors was authorized to grant up to 2,538,125 additional warrants to our employees, board members and select consultants without preemptive subscription rights for the shareholders of Ascendis Pharma A/S. Each warrant carries the right to subscribe for one ordinary share of a nominal value of DKK 1. The exercise price is fixed at the fair market value of our ordinary shares at the time of grant as determined by our board of directors. Vested warrants may be exercised in two or four annual exercise periods as described below. Apart from exercise prices and exercise periods, the programs are similar.

Vesting Conditions

Warrants issued during the period from 2008 to 2012 generally vested over 36 months with 1/36 of the warrants vesting per month from the date of grant. However, some of these warrants were subject to shorter vesting periods, to a minimum of 24 months. All such warrants have been exercised or have expired as of December 31, 2018.

Effective from and after December 2012, warrants granted generally vest over 48 months with 1/48 of the warrants vesting per month from the date of grant.

Effective from and after December 2016, certain warrants issued to board members vest over 24 months with 1/24 of the warrants vesting per month from the date of grant.

Warrants generally cease to vest from the date of termination in the event that (i) the warrantholder terminates the employment contract and the termination is not a result of breach of the employment terms by us, or (ii) in the event that we terminate the employment contract and the warrantholder has given us good reason to do so. The warrantholder will, however, be entitled to exercise vested warrants in the first exercise period after termination.

In the event that we terminate the employment contract and the warrantholder has not given us good reason to do so, the warrantholder may keep the right to continued vesting and exercise of warrants as if the employment was still in effect. In such case, any expense not yet recognized for the outstanding warrants is recognized immediately.

Warrants issued to consultants, advisors and board members only vest so long as the consultant, advisor or board member continues to provide services to us.

Exercise Periods

Vested warrants may be exercised during certain exercise periods each year. For 657,749 outstanding warrants, there are two annual exercise periods that continue for 21 days from and including the day after the publication of (i) the annual report notification—or if such notification is not published—the annual report and (ii) our interim report (six-month report). For these warrants, the last exercise period is 21 days from and including the day after the publication of our interim report for the first half of 2023. For 272,997 outstanding warrants granted in connection with our Preference D financing, there are four annual exercise periods that continue for 21 days following the day of publication of (i) our interim report (three-month report); (ii) the annual report notification—or if such notification is not published—the annual report; (iii) our interim report (six-month report); and (iv) our interim report (nine-month report). For these warrants, the last exercise period is 21 days following the publication of our interim report (nine-month report) in 2023. For 4,680,883 warrants granted on or after December 18, 2015, there are four annual exercise periods; each exercise period begins two full trading days after the publication of the public release of our earnings data of a fiscal quarter and continues until the end of the second-to-last trading day in which quarter the relevant earnings release is published. The warrants granted in December 2015 and later expire ten years after the grant date.

In the event of liquidation, a merger, a demerger or a sale or share exchange of more than 50% of our share capital, the warrantholders may be granted an extraordinary exercise period immediately prior to the transaction in which warrants may be exercised.

Warrants not exercised by the warrantholder during the last exercise period shall become null and void without further notice or compensation or payment of any kind to the warrantholder.

If the warrantholder is a consultant, advisor or board member, the exercise of warrants is conditional upon the warrantholder’s continued service to us at the time the warrants are exercised. If the consultant’s, advisor’s or board member’s relationship with us should cease without this being attributable to the warrantholder’s actions or omissions, the warrantholder shall be entitled to exercise vested warrants in the pre-defined exercise periods.

Adjustments

Warrantholders are entitled to an adjustment of the number of warrants issued and/or the exercise price applicable in the event of certain corporate changes. Events giving rise to an adjustment include, among other things, increases or decreases to our share capital at a price below or above market value, respectively, the issuance of bonus shares, changes in the nominal value of each share, and payment of dividends in excess of 10% of the Company’s equity.

On January 13, 2015, in preparation for the Company’s IPO, the shareholders decided at an extraordinary general meeting to issue bonus shares in the ratio of 3:1 of the Company’s authorized, issued and outstanding ordinary and preference shares. The decision had a corresponding impact on the number of warrants issued and the exercise prices for outstanding warrants. Accordingly, the number of warrants was adjusted upwards in the ratio of 3:1 with a corresponding downward adjustment of the exercise prices in the ratio of 3:1. The effect of the bonus shares has been retrospectively reflected in all periods presented in these consolidated financial statements.

Warrant Activity

Warrant compensation cost is recognized in the consolidated statement of profit or loss over the vesting period of the warrants granted.

	2018	2017	2016
		(EUR'000)	
Research and development costs	10,225	4,775	3,722
General and administrative expenses	9,427	4,934	3,599
Total warrant compensation costs	**19,652**	**9,709**	**7,321**

The following table specifies number and weighted average exercise prices of, and movements in warrants during the year:

	Total Warrants	Weighted Average Exercise Price EUR
Outstanding at January 1, 2016	2,615,903	**10.69**
Granted during the year	1,202,500	17.69
Exercised during the year (1)	(115,212)	7.63
Forfeited during the year	(11,426)	13.88
Expired during the year	—	—
Outstanding at December 31, 2016	**3,691,765**	**13.05**
Vested at the balance sheet date	**1,439,066**	**9.36**
Granted during the year	1,196,000	30.15
Exercised during the year (1)	(193,171)	8.49
Forfeited during the year	(73,440)	16.42
Expired during the year	—	—
Outstanding at December 31, 2017	**4,621,154**	**17.62**
Vested at the balance sheet date	**2,034,791**	**11.48**
Granted during the year	1,637,375	54.43
Exercised during the year (1)	(611,683)	10.82
Forfeited during the year	(35,217)	28.24
Expired during the year	—	—
Outstanding at December 31, 2018	5,611,629	29.03
Vested at the balance sheet date	**2,478,770**	**15.81**

(1) The weighted average share price (issued in $) at the date of exercise was €58.01, €26.75, and €16.74 for the financial years ended December 31, 2018, 2017, and 2016, respectively.

The following table specifies the weighted average exercise prices and weighted average remaining contractual life for outstanding warrants at December 31, 2018, per grant year.

	Number of Outstanding Warrants	Weighted Average Exercise Price EUR	Weighted Average Remaining Life (months)
Granted in 2012	532,011	8.00	56
Granted in 2013	83,738	8.00	56
Granted in 2014	314,997	6.78	59
Granted in 2015	815,895	15.67	83
Granted in 2016	1,067,469	17.89	93
Granted in 2017	1,164,144	30.15	106
Granted in 2018	1,633,375	54.43	118
Outstanding at December 31, 2018	**5,611,629**	**29.03**	**96**

At December 31, 2018, the exercise prices of outstanding warrants under our warrant programs range from €6.48 to €60.23 depending on the grant dates.

The range of exercise prices for outstanding warrants was €6.48 - €31.60, and €6.48 - €19.42, for the financial years ended December 31, 2017, and 2016, respectively. The weighted average remaining life for outstanding warrants was 112 months and 109 months, for the financial years ended December 31, 2017, and 2016, respectively.

Warrant Compensation Costs

Warrant compensation costs are determined with basis in the grant date fair value of the warrants granted and recognized over the vesting period. Fair value of the warrants is calculated at the grant dates by use of the Black-Scholes Option Pricing model with the following assumptions: (1) an exercise price equal to or above the estimated market price of our shares at the date of grant; (2) an expected lifetime of the warrants determined as a weighted average of the time from grant date to date of becoming exercisable and from grant date to expiry of the warrants; (3) a risk free interest rate equaling the effective interest rate on a Danish government bond with the same lifetime as the warrants; (4) no payment of dividends; and (5) a volatility for comparable companies for a historic period equaling the expected lifetime of the warrants. The expected volatility reflects the assumption that the historical volatility over a period similar to the life of the warrants is indicative of future trends. The expected volatility has been calculated using a simple average of daily historical data of comparable publicly traded companies, as we do not have sufficient data for the volatility of our own share price.

The following table summarizes the input to the Black-Scholes Option Pricing model and the calculated fair values for warrant grants in 2018, 2017 and 2016:

	2018	2017	2016
Expected volatility	53 – 57%	54 — 60%	57 — 60%
Risk-free interest rate	(0.23) – 0.46%	(0.34) — 0.25%	(0.32) — 0.30%
Expected life of warrants (years)	5.05 – 7.14	5.05 — 7.10	5.05 — 7.13
Weighted average exercise price	EUR 54.43	EUR 30.15	EUR 17.69
Fair value of warrants granted in the year	EUR 17.90 – 31.81	EUR 9.65 — 17.29	EUR 5.78 — 11.07

Note 7—Finance Income and Finance Expenses

	2018	2017	2016
		(EUR'000)	
Interest income	4,020	923	123
Exchange rate gains	20,694	—	7,177
Total finance income	**24,714**	**923**	**7,300**
Interest expense	(127)	(97)	(5)
Exchange rate losses	—	(13,659)	(3,107)
Total finance expenses	**(127)**	**(13,756)**	**(3,112)**

Interest income and expenses relates to financial assets and liabilities measured at amortized cost.

Note 8—Tax on Profit/(Loss) for the Year and Deferred Tax

	2018	2017	2016
		(EUR'000)	
Tax on profit/(loss) for the year:			
Current tax (expense)/income	394	477	227
	394	**477**	**227**
Tax for the year can be explained as follows:			
Profit/(loss) before tax	(130,491)	(124,374)	(68,732)
Tax at the Danish corporation tax rate of 22%	**28,708**	**27,362**	**15,121**
Tax effect of:			
Non-deductible costs	(4,327)	(1,553)	(1,153)
Additional tax deductions	4,074	356	65
Share of profit/(loss) of associate	(71)	—	—
Unrecognized deferred tax from associate	(2,312)	—	—
Tax credits	—	(1,028)	(740)
Other effects including effect of different tax rates	143	598	266
Valuation adjustments on deferred tax assets	(25,821)	(25,258)	(13,332)
Tax on profit/(loss) for the year	**394**	**477**	**227**
Effective tax rate	**(0.30)%**	**(0.38)%**	**(0.33)%**

No changes to deferred tax has been recognized in the consolidated statement of profit or loss for 2018, 2017 or 2016.

	2018	2017	2016
		(EUR'000)	
Specification of Deferred Tax Asset			
Tax deductible losses	(74,120)	(52,084)	(27,188)
Deferred income	(3,092)	(86)	(144)
Other temporary differences	(1,324)	(545)	(124)
Valuation allowances	78,536	52,715	27,456
Total Deferred Tax Asset at December 31	**0**	**0**	**0**

The deferred tax assets have not been recognized in the consolidated statements of financial position due to uncertainty relating to the future utilization. The deferred tax asset can be carried forward without timing limitations. For tax losses carried forward, certain limitations exist for amounts to be utilized each year.

Under Danish tax legislation, tax losses may be partly refunded by the tax authorities to the extent such tax losses arise from research and development activities. For the year ended December 31, 2018, the jointly taxed Danish entities had a negative taxable income, and accordingly were entitled to a tax refund of approximately €0.7 million, compared to approximately €0.7 million and €0.7 million for the years ended December 31, 2017 and 2016, respectively.

The parent company Ascendis Pharma A/S is jointly taxed with its Danish subsidiaries. The current Danish corporation tax is allocated between the jointly taxed Danish companies in proportion to their taxable income (full absorption with refunds for tax losses). These companies are taxed under the on-account tax scheme.

Note 9—Intangible Assets

	Goodwill (EUR'000)
Cost:	
At January 1, 2017	**3,495**
Additions	—
December 31, 2017	**3,495**
Additions	—
December 31, 2018	**3,495**
Accumulated impairment:	
At January 1, 2017	**—**
Impairment charge	—
At December 31, 2017	**—**
Impairment charge	—
At December 31, 2018	**—**
Carrying amount:	
At December 31, 2018	**3,495**
At December 31, 2017	**3,495**

Due to the risk associated with drug development, future income from development projects cannot be determined with sufficient certainty until the development activities have been completed and the necessary marketing approvals have been obtained. Accordingly, we do not recognize internally generated intangible assets at this time. Thus, all research and development costs incurred for the financial years ended December 31, 2018, 2017 and 2016, were recognized in the consolidated statement of profit or loss.

Goodwill relates to the acquisition of Complex Biosystems GmbH (now Ascendis Pharma GmbH) in 2007. Goodwill was calculated as the excess amount of the purchase price to the fair value of identifiable assets acquired, and liabilities assumed at the acquisition date. Business combinations recognized before January 1, 2012, the Company's date of transition to IFRS, have not been adjusted to IFRS 3, "Business Combinations". Ascendis Pharma GmbH was initially a separate technology platform company but is now an integral part of our research and development activities, including significant participation in the development services provided to our external collaboration partners. Accordingly, it is not possible to look separately at Ascendis Pharma GmbH when considering the recoverable amount of the goodwill. Goodwill is monitored and tested for impairment on a consolidated level as we are considered to represent one cash-generating unit. The recoverable amount of the cash-generating unit is determined based on an estimation of the Company's fair value less costs of disposal. We have determined the fair value of goodwill after taking into account the market value of our ADSs representing the enterprise value of our group enterprises as of the balance sheet date. The computation of our enterprise value significantly exceeded the carrying amount of our equity, leaving sufficient value to cover the carrying amount of goodwill. With reference to materiality, we have concluded that no further assumptions need to be applied in determining whether goodwill is impaired.

Goodwill is tested for impairment on an annual basis at December 31, or more frequently, if indications of impairment are identified. There have been no impairments recognized in any of the periods presented.

Note 10—Property, Plant and Equipment

	Plant and Machinery	Other Equipment	Leasehold Improve-ments	Total
		(EUR'000)		
Cost:				
At January 1, 2017	**3,967**	**1,494**	**620**	**6,081**
Additions	540	371	30	941
Disposals	—	(224)	—	(224)
At December 31, 2017	**4,507**	**1,641**	**650**	**6,798**
Additions	1,206	1,270	225	2,701
Disposals	(68)	(316)	—	(384)
At December 31, 2018	**5,645**	**2,595**	**875**	**9,115**
Accumulated depreciation:				
At January 1, 2017	**(2,676)**	**(786)**	**(269)**	**(3,731)**
Depreciation charge	(378)	(292)	(64)	(734)
Disposals	—	224	—	224
At December 31, 2017	**(3,054)**	**(854)**	**(333)**	**(4,241)**
Depreciation charge	(410)	(415)	(55)	(880)
Disposals	16	315	—	331
December 31, 2018	**(3,448)**	**(954)**	**(388)**	**(4,790)**
Carrying amount:				
At December 31, 2018	**2,197**	**1,641**	**487**	**4,325**
At December 31, 2017	**1,453**	**787**	**317**	**2,557**

Included in leasehold improvements at December 31, 2018 was an amount of €222 thousand (2017: €0 thousand) relating to expenditure for improvements under construction.

	2018	2017	2016
		(EUR'000)	
Depreciation charges are recognized as:			
Research and development costs	(827)	(701)	(645)
General and administrative expenses	(53)	(33)	(32)
Total depreciation charges	**(880)**	**(734)**	**(677)**

Note 11—Investments in Group Enterprises

Investments in Group enterprises comprise:

Subsidiaries	Domicile	Ownership
Ascendis Pharma GmbH	Germany	100%
Ascendis Pharma, Inc.	USA	100%
Ascendis Pharma Ophthalmology Division A/S	Denmark	100%

Subsidiaries	Domicile	Ownership
Ascendis Pharma Endocrinology Division A/S	Denmark	100%
Ascendis Pharma Bone Diseases A/S	Denmark	100%
Ascendis Pharma Growth Disorders A/S	Denmark	100%
Associate		
VISEN Pharmaceuticals	Cayman Island	50%

Note 12 —Investment in Associate

VISEN Pharmaceuticals ("VISEN") was formed in November 2018. The Company has granted VISEN exclusive rights to develop and commercialize TransCon hGH, TransCon PTH and TransCon CNP in Greater China (the "Territory"), and as consideration for the granting of such rights has received a 50% ownership of VISEN. The other investors contributed, in aggregate, $40 million in cash as their consideration for remaining 50% ownership.

VISEN is a private entity not listed on any public exchange, with business activities within developing, manufacturing and commercialization of endocrinology rare disease therapies in the Territory. The Company's interest in VISEN is accounted for as an associate using the equity method in the consolidated financial statements as the Company has determined that it has significant influence but not joint control.

The following table illustrates the summarized relevant financial information of our investment in VISEN.

	2018
VISEN Pharmaceuticals	
Principal place of business	Cayman Island
Ownership	50%
	(EUR'000)
Profit or loss	
Profit / (loss) for the year	(642)
Financial position	
Non-current assets	34,819
Current assets	34,155
Non-current liabilities	—
Current liabilities	9
Equity	68,965
Company's share of equity before eliminations	**34,483**
Elimination of profit recognized at December 31	*(17,400)*
Company's share of equity	**17,083**
Investment in associate at December 31	**17,083**

VISEN requires the Company's consent to distribute dividend and incur indebtedness outside the normal course of business. At the reporting date, the Company has not given such consent.

VISEN had no contingent liabilities or capital commitments as at December 31, 2018. At the date these consolidated financial statements are authorized for use, no events have occurred after the balance sheet date that would influence the evaluation of these consolidated financial statements.

Transactions with VISEN in 2018 relate to the grant of three exclusive licenses, whereby the Company has received non-cash consideration in form of 40,000,000 shares in VISEN in return, reflecting a fair value of $40 million.

In the consolidated financial statements for 2018, €10.5 million was recognized as license income in the profit or loss, and €6.9 million is recognized as contract liabilities (deferred income) in the consolidated statement of financial position. Please refer to note 4 and note 15.

There are no trade balances held relating to VISEN at December 31, 2018. Similarly, no loans have been granted to or obtained from VISEN, respectively.

Note 13—Share Capital

The share capital of Ascendis Pharma A/S consists of 42,135,448 fully paid shares at a nominal value of DKK 1, all in the same share class.

The number of shares of the Company are as follows:

	2018	2017	2016	2015	2014
Changes in share capital					
Beginning of year	36,984,292	32,421,121	25,128,242	16,935,780	10,801,948
Increase through cash contribution	5,151,156	4,563,171	7,292,879	8,192,462	6,133,832
End of year	**42,135,448**	**36,984,292**	**32,421,121**	**25,128,242**	**16,935,780**

Note 14—Distributable Equity

Share Premium Reserve

Share premium comprises the amounts received, attributable to shareholders' equity, in excess of the nominal amount of the shares issued at the parent company's capital increases, reduced by any expenses directly attributable to the capital increases. Under Danish legislation, share premium is an unrestricted reserve that is available to be distributed as dividends to a company's shareholders. Also, under Danish legislation, the share premium reserve can be used to offset accumulated deficits.

Foreign Currency Translation Reserve

Exchange rate differences relating to the translation of the results and net assets of our foreign operations and associate from their functional currencies to our presentation currency are recognized directly in other comprehensive income and accumulated in the foreign currency translation reserve. The foreign currency translation reserve is an unrestricted reserve that is available to be distributed as dividends to a company's shareholders.

Share-Based Payment Reserve

Warrants granted under our employee warrant program carry no rights to dividends and no voting rights. The share-based payment reserve represents the fair value of warrants recognized from grant date. Further details of the employee warrant program are provided in Note 6. Share-based payment reserve is an unrestricted reserve that is available to be distributed as dividends to a company's shareholders.

Retained Earnings or Accumulated Deficits

Retained earnings or accumulated deficits represent the accumulated profit or losses from the Company's operations. A positive balance of retained earnings is available to be distributed as dividends to a company's shareholders.

Note 15—Contract liabilities

Deferred income was €6.9 million and €0 million, for the financial years ended December 31, 2018 and 2017, respectively, and relate to partially satisfied performance obligations due to our ongoing research and development of licensed product candidates.

The majority of the deferred income relating to partially satisfied performance obligations recognized at December 31, 2018, are expected to be recognized as revenue in 2019.

Note 16—Commitments and Contingencies

Operating Leases

We operate from leased premises in Denmark, Germany and the US. In addition, we have entered into operating leases for equipment. The total lease commitment (minimum lease payments) under operating leases was:

	2018	2017
	(EUR'000)	
Within 1 year	4,220	2,951
Within 1 to 5 years	11,798	12,485
After 5 years	3,609	3,957
Total commitments held under operating leases	**19,627**	**19,393**

Lease arrangements regarding our premises are subject to extension options, providing us with the right (not obligation) to extend the lease after the initial term. Other than already exercised extension options, no extension options are deemed reasonably certain to be exercised at December 31, 2018.

Total expenses under operating leases were €2.7 million, €1.6 million, and €1.5 million for the financial years ended December 31, 2018, 2017, and 2016, respectively.

Of other contractual commitments, the Company has entered into service contracts of various lengths in respect of research and development, IT- and facility related services. Costs relating to the contracts are recognized as services are received.

Note 17—Financial Risk Management and Financial Instruments

Our financial assets and liabilities comprise the following;

	2018	2017
	(EUR'000)	
Financial assets:		
Deposits	1,158	293
Trade receivables	6	188
Cash and cash equivalents	277,862	195,351
Financial assets measured at amortized cost	**279,026**	**195,832**
Financial liabilities		
Trade payables	19,740	17,434
Financial liabilities measured at amortized cost	**19,740**	**17,434**

The carrying amounts of the financial assets and financial liabilities are estimated being in line with the fair value due to the short-term nature of the balances.

Capital Management

We manage our capital to ensure that all group enterprises will be able to continue as going concerns while maximizing the return to shareholders through the optimization of our debt and equity balance. Our overall strategy in this regard has remained unchanged since 2012.

Our capital structure consists only of equity comprising issued capital, reserves and retained earnings. We do not hold any external debt.

We are not subject to any externally imposed capital requirements. We review our capital structure on an ongoing basis. As we do not have external debt, such review currently comprises a review of the adequacy of our capital compared to the resources required for carrying out our activities.

Financial Risk Management Objectives

We regularly monitor the access to domestic and international financial markets, manage the financial risks relating to our operations, and analyze exposures to risk, including market risk, such as currency risk and interest rate risk, credit risk and liquidity risk.

We seek to minimize the effects of these risks by managing transactions and holding positions in the various currencies used in our operations. We do not enter or trade financial instruments for speculative purposes.

Market Risk

Our activities primarily expose our group enterprises to the financial risks of changes in foreign currency exchange rates and interest rates. We do not enter derivative financial instruments to manage our exposure to such risks.

Foreign Currency Risk Management

Our foreign exchange rate risks are unchanged to prior year. We are exposed to foreign exchange risks arising from various currency exposures, primarily with respect to the US Dollar, the British Pound and the Danish Krone.

Future milestone payments, which we are entitled to upon meeting underlying thresholds, are dominated in US Dollar. Further, the proceeds from our series D financing in November 2014, our IPO in February 2015 and our follow-on offerings in October 2016, September 2017 and February 2018 were in US Dollars. We seek to minimize our exchange rate risk by maintaining cash positions in the currencies in which we expect to incur the majority of our future expenses and we make payments from those reserves.

Foreign Currency Sensitivity Analysis

We are primarily exposed to US Dollars (USD), British Pounds (GBP), and Danish Kroner (DKK). There is an official target zone of 4.50% between DKK and EUR, which limits the likelihood of significant fluctuations between those two currencies in a short time-frame.

The following table details our sensitivity to a 10% increase and decrease in EUR against USD and GBP, respectively. 10% represents our assessment of the reasonably possible change in foreign currency rates. The sensitivity analysis includes only outstanding foreign currency denominated monetary items and adjusts their translation at the period-end for a 10% change in foreign currency rate. A positive number indicates an increase in profit and equity before tax, while a negative number indicates opposite. We believe the sensitivity analysis is representative of the inherent foreign exchange risk associated with our operations.

		Hypothetical impact on consolidated financial statements		
2018	Nominal positions (EUR '000)	Increase in foreign exchange rate	Profit or loss before tax	Equity before tax
USD/EUR	178,308	10%	17,831	17,831
GBP/EUR	(816)	10%	(82)	(82)

2017	Nominal positions (EUR '000)	Hypothetical impact on consolidated financial statements: Increase in foreign exchange rate	Profit or loss before tax	Equity before tax
USD/EUR	183,362	10%	18,336	18,336
GBP/EUR	1,163	10%	116	116

Interest Rate Risk Management

As we have no interest-bearing debt to third parties, derivatives or financial assets and liabilities measured at fair value, our exposure to interest rate risk primarily relates to the interest rates for our positions of cash and cash equivalents. Our future interest income from interest-bearing bank deposits and short-term investments may fall short of expectations due to changes in interest rates. We do not consider the effects of interest rate fluctuations to be a material risk to our financial position. Accordingly, no interest sensitivity analysis has been presented.

Credit Risk Management

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss. We consider all of our material counterparties to be creditworthy. Our exposure to credit risk is continuously monitored, in particular, if agreed payments are delayed.

While the concentration of credit risk is significant, we consider the credit risk for each of our individual counterparts to be low. Accordingly, since we had no significant trade receivables at December 31, 2018 or December 31, 2017, and our deposits are held with suppliers that are frequently used in our operations, we have made no provision for trade receivables or deposits.

Our maximum exposure to credit risk primarily relates to our cash and cash equivalents. The credit risk on cash and cash equivalents is limited because the counterparties, holding significant deposits, are banks with high credit-ratings assigned by international credit-rating agencies.

The banks are reviewed on a regularly basis and our deposits may be transferred during the year to mitigate credit risk.

We have considered the risk of Expected Credit Loss over our cash deposits, including the hypothetical impact arising from the probability of default (past due with 90 days) considering in conjunction with the expected loss given default from banks with similar credit rating and attributes. Our assessment did not reveal an expected material impairment loss, and accordingly we have made no provision for bank deposits.

Liquidity Risk Management

We manage our liquidity risk by maintaining adequate cash reserves and banking facilities, and by continuously monitoring our cash forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities. We monitor the risk of a shortage of funds using a liquidity planning tool, to ensure enough funds available to settle liabilities as they fall due. We do not hold any long-term interest-bearing debt, and accordingly all financial liabilities fall due within 12 months.

Historically we have addressed the risk of insufficient funds through proceeds from our series D financing, our IPO, and our follow-on public offerings. The Company's Board of Directors has, at the time of approving the consolidated financial statements, a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future.

Note 18—Related Party Transactions

The Board of Directors and Executive Board (Key Management Personnel) are considered related parties as they have authorities and responsibilities with planning and directing our operations. Related parties also include undertakings in which such individuals have a controlling or joint controlling interest. Additionally, all our group enterprises and our associate are considered related parties.

Neither our related parties nor our major shareholders hold a controlling or joint controlling interest in the Group.

We have entered into employment agreements with and issued warrants to Key Management Personnel. In addition, we are paying fees for board tenure and board committee tenure to the independent members of our Board of Directors. Please refer to note 6.

Transactions between group enterprises comprise management and license fees, research & development services, and clinical supplies. These transactions have been eliminated in the consolidated financial statements. Transactions and outstanding balances with our associate VISEN are disclosed in note 12.

We have entered into indemnification agreements with our board members and members of our senior management.

Except for the information disclosed above, we have not undertaken any significant transactions with members of the Key Management Personnel, or undertakings in which the identified related parties have a controlling or joint controlling interest.

Note 19—Ownership

The following persons, or groups of affiliated persons, are known by us to beneficially own more than 5% of our outstanding ordinary shares:

- Entities affiliated with RA Capital Management, LLC, USA
- OrbiMed Private Investments V, L.P., USA
- Entities affiliated with FMR LLC, USA
- Baker Bros. Advisors LP
- T. Rowe Price Associates, Inc., USA
- Entities affiliated with Vivo Capital, USA

The Company's American Depository Shares are held through BNY (Nominees) Limited as nominee, of The Bank of New York Mellon, UK (as registered holder of the Company's outstanding ADSs).

Note 20—Subsequent Events

On March 5, 2019, the Company entered into an underwriting agreement with J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Credit Suisse Securities (USA) LLC, and Evercore Group L.L.C., as representatives of the several underwriters named therein (collectively, the "Underwriters"), pursuant to which the Company agreed to issue and sell 4,166,667 ADSs to the Underwriters (the "March 2019 Offering"). The ADSs were sold at a public offering price of $120.00 per ADS and were purchased by the Underwriters from the Company at a price of $112.80 per ADS. Under the terms of the Underwriting Agreement, the Company granted the Underwriters the right, for 30 days, to purchase from the Company up to 625,000 additional ADSs at the public offering price, less the underwriting commissions. On March 11, 2019, the Underwriters exercised their option in full to purchase the additional 625,000 ADSs.

On March 14, 2019, the March 2019 Offering closed and the Company completed the sale and issuance of an aggregate of 4,791,667 ADSs. The Company received net proceeds from the March 2019 Offering of approximately $539.8 million, or €476.9 million at the date of closing, after deducting the Underwriters' commissions and the Company's estimated offering expenses.

No other events have occurred after the balance sheet date that would influence the evaluation of these consolidated financial statements.

Table of Contents

Item 19 *Exhibits*

The following exhibits are filed as part of this annual report:

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	Date	Number	File Number	
1.1	Articles of Association, currently in effect (English translation).	6-K	3/14/2019	1.1	001-36815	
2.1	Deposit Agreement dated January 27, 2015 among Ascendis Pharma A/S The Bank of New York Mellon and Owners and Holders of American Depositary Shares.	F-3	2/2/2016	4.2	333-209336	
2.2	Form of American Depositary Receipt (included in Exhibit 2.1).					
4.1†	Exclusive Licence Agreement dated July 31, 2013 between Ascendis Pharma Ophthalmology Division A/S, Genentech, Inc. and F. Hoffmann-La Roche Ltd.	F-1	12/18/2014	10.1	333-201050	
4.2†	Patent Transfer & Exclusive Licence Agreement dated December 15, 2010 between Ascendis Pharma A/S and Sanofi Aventis Deutschland GmbH.	F-1	12/18/2014	10.2	333-201050	
4.3(a)	Rental Agreement, between Technologiepark Heidelberg II GmbH & Co. KG and Ascendis Pharma GmbH (English translation).	F-1	12/18/2014	10.3(a)	333-201050	
4.3(b)	Supplement No. 1 to Rental Agreement, between Technologiepark Heidelberg II GmbH & Co. KG and Ascendis Pharma GmbH (English translation).	F-1	12/18/2014	10.3(b)	333-201050	
4.4(a)#	Reference is made to Exhibit 1.1.					
4.4(b)#	Form of Warrant Certificate for Warrants issued prior to December 2015.	F-1	12/18/2014	10.4(b)	333-201050	
4.4(c)#	Form of Warrant Certificate for Warrants issued since December 2015.	20-F	3/22/2017	4.4(c)	001-36815	
4.5#	Form of Indemnification Agreement for board members and senior management.	F-1	1/16/2014	10.5	333-201050	
4.6(a)	Registration Rights Agreement dated November 24, 2014 among Ascendis Pharma A/S and the investors set forth therein.	F-1	12/18/2014	10.6	333-201050	

4.6(b)	First Amendment to Registration Rights Agreement dated December 11, 2015 by and among Ascendis Pharma A/S and the investors set forth therein.	6-K	12/14/2015	4.2	001-36815	
4.7	Registration Rights Agreement dated December 11, 2015 by and among Ascendis Pharma A/S, Fidelity Securities Fund: Fidelity Series Small Cap Opportunities Fund—Healthcare Sub and Fidelity Stock Selector Small Cap Fund—Health Care Sub.	6-K	12/14/2015	4.1	001-36815	
4.8	Lease Agreement dated September 7, 2015 between Ascendis Pharma A/S and Dades AS.	F-3	2/2/2016	10.1	001-36815	
4.9†	Manufacturing and Supply Agreement dated December 21, 2017, between Ascendis Pharma A/S and NOF Corporation.	20-F	3/28/2018	4.9	001-36815	
4.10†	Manufacturing and Supply Agreement dated January 12, 2017, between Ascendis Pharma A/S and Medicom Innovation Partner a/s.	20-F	3/28/2018	4.10	001-36815	
4.11*	Supply Agreement dated January 1, 2019, between Ascendis Pharma A/S and Vetter Pharma International GMBH.					X
4.12*	Manufacturing and Supply Agreement dated October 28, 2018, between Ascendis Pharma A/S and Carbogen Amcis AG.					X
4.13*	Commercial Supply Agreement dated January 9, 2019, between Ascendis Pharma A/S and Fujifilm Diosynth Biotechnologies UK Limited.					X
4.14*	Shareholders Agreement dated November 7, 2018, by and among Ascendis Pharma A/S and the parties set forth therein.					X
4.15*	Exclusive Licence Agreement dated November 7, 2018, between Ascendis Pharma Endocrinology Division A/S and Visen Pharmaceuticals (CNP).					X
4.16*	Exclusive Licence Agreement dated November 7, 2018, between Ascendis. Pharma Endocrinology Division A/S and Visen Pharmaceuticals (hGH).					X
4.17*	Exclusive Licence Agreement dated November 7, 2018, between Ascendis Pharma Endocrinology Division A/S and Visen Pharmaceuticals (PTH).					X
8.1	List of Subsidiaries.					X
12.1	Certification by Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X

12.2	Certification by Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X
13.1	Certification by Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
13.2	Certification by Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
15.1	Consent of Independent Registered Public Accounting Firm.	X
EX-101.INS	XBRL Instance Document.	X
EX-101.SCH	XBRL Taxonomy Extension Schema Document.	X
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X
EX-101.IAB	XBRL Taxonomy Extension Labels Linkbase Document.	X
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X

† Confidential treatment has been granted for certain information contained in this Exhibit. Such information has been omitted and filed separately with the SEC.

# Indicates senior management contract or compensatory plan.

* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10). Such omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

Table of Contents

Signatures

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Ascendis Pharma A/S

By: /s/ Jan Møller Mikkelsen

Jan Møller Mikkelsen

President, Chief Executive Officer, Board Member and Executive Director (Principal Executive Officer)

Date: April 3, 2019

By: /s/ Scott T. Smith

Scott T. Smith

Senior Vice President, Chief Financial Officer (Principal Financial Officer)

Date: April 3, 2019

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

SUPPLY AGREEMENT

for manufacture and supply of dual-chamber cartridges [***], pre-filled with TransCon [***] hGH and Water for Injection, delivered [***]

effective as of January 1st, 2019

by and between

ASCENDIS PHARMA A/S

and

VETTER PHARMA INTERNATIONAL GMBH

TABLE OF CONTENTS

THIS SUPPLY AGREEMENT, made and entered into as of the date written above (hereinafter, this "Agreement"), by and between *Ascendis Pharma A/S*, a company duly organized and existing under the laws of *Denmark* and having its place of business located at *Tuborg Boulevard 12, 2900 Hellerup, Denmark* ("Ascendis"), and *Vetter Pharma International GmbH*, a company duly organized and existing under the laws of *Germany*, having its principal place of business at *Eywiesenstraße 5, 88212 Ravensburg, Germany* ("Vetter International") and owned 100% by *Vetter Pharma-Fertigung GmbH & Co. KG ("Vetter Pharma"),*

W I T N E S S E T H:

WHEREAS, Ascendis desires the Manufacture and supply of dual-chamber cartridges [***], pre-filled with TransCon [***] hGH and Water for Injection, delivered [***] for use within the Territory;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements hereinafter set forth, and subject to the terms and conditions of this Agreement, Ascendis and Vetter International agree as follows:

ARTICLE 1: DEFINITIONS

For all purposes of this Agreement, and all amendments thereto, the following capitalized terms, whether used in the singular or plural, shall have the same and uniform meanings as below defined and specified, unless the context otherwise requires:

(1) "Affiliate" shall in respect of Ascendis mean any person, firm, company, or entity which is directly or indirectly controlled by Ascendis, and with respect to Vetter International, any person, firm, company, or entity which is under common control of the trustees/executors of the estate of *Helmut Vetter.* For all purposes hereof, "control" shall mean owning more than fifty percent (50%) of the voting stock or interests.

(2) "Agreed Specifications" shall have the meaning set forth in the Commercial Quality Agreement.

(3) "Agreement" shall mean this supply agreement and its Annexes, specifically including the Commercial Quality Agreement.

(4) "Annex" shall mean an annex attached to this Agreement.

(5) "API" shall mean TransCon [***] hGH as specified in Appendix 2 of the Commercial Quality Agreement.

(6) "API Invention" shall have the meaning set forth in Section 11(2).

(7) "Appendix" shall mean an appendix attached to the Commercial Quality Agreement.

(8) "Article" shall mean an article of this Agreement (excluding the Commercial Quality Agreement).

(9) "Ascendis" shall have the meaning set forth first above.

(10) "Ascendis Disclosed Manufacture IP" shall have the meaning set forth in Section 11(3).

(11) "Ascendis Materials" shall mean the materials provided by Ascendis including API as further detailed in the Commercial Quality Agreement.

(12) "Business Day" shall mean any calendar day other than a Saturday, a Sunday or a calendar day on which commercial banks located in Baden-Württemberg, Germany or Denmark, are authorized or required by law to be closed.

(13) "Commercial Quality Agreement" shall mean the commercial quality agreement, including all Appendices, attached hereto as Annex 4, which Vetter International shall cause Vetter Pharma to enter into with respect to the quality of the Product.

(14) "Completion Date" shall have the meaning set forth in Section 14(1).

(15) "Confidential Information" shall have the meaning set forth in Section 16 (2).

(16) "Costs and Liabilities" shall mean damages, liabilities, claims, suits, awards, judgments, costs and/or expenses, including any court costs and/or reasonable attorneys' fees.

(17) "Critical Deviations" shall have the meaning set forth in the Commercial Quality Agreement.

(18) "DCC" shall mean Dual Chamber Cartridge

(19) "Delivery Date" means the date that Product shall be delivered pursuant to the Business Day specified by Ascendis in the Purchase Order confirmed by Vetter International in writing [***].

(20) "Deviations" shall have the meaning set forth in the Commercial Quality Agreement.

(21) "Discloser" shall have the meaning set forth in Section 16(1).

(22) "Effective Date" shall mean the day and year set forth first above.

(23) "EMA" shall mean the *European Medicines Agency*, or any successor agency.

(24) "Equipment" shall mean the equipment in more detail set forth in Annex 3.

(25) "Facility" shall mean the manufacturing and logistics facilities used for the Manufacture and located in or near [***].

(26) "FDA" shall mean the *Food and Drug Administration* of the *United States of America,* or any successor agency.

(27) "Final Release" shall have the meaning defined in Section 8(2) (b).

(28) "Force Majeure" shall have the meaning set forth in Section 17(1).

(29) "GMP" shall have the meaning set forth in the Commercial Quality Agreement.

(30) "Information of Ascendis" shall have the meaning set forth in the Commercial Quality Agreement and referred to by the respective Appendix thereof.

(31) "Initial Term" shall have the meaning as set forth in Section 14 (1).

(32) "IP" shall have the meaning set forth in Section 11(1).

(33) "Joint Project Steering Committee" or "JPSC" shall have the meaning set forth in Section 2 (5).

(34) "Major Deviations" shall have the meaning set forth in the Commercial Quality Agreement.

(35) "Manufacture" or "Manufacturing" shall have the meaning set forth in the Commercial Quality Agreement.

(36) "Manufacture Invention" shall have the meaning set forth in Section 11(3).

(37) "Non-Conformance" or "Non-Conforming" shall mean with respect to a Product or batch of Product failure to conform to the Standard and having a significant impact with regard to GMP compliance or the Product quality.

(38) "Parties" shall mean Ascendis and Vetter International, and "Party" shall mean either thereof.

(39) "Purchase Order" shall mean a document issued by Ascendis and sent for confirmation to Vetter International constituting a binding commitment to purchase a specified quantity of Product for delivery on a requested Delivery Date.

(40) "PPQ" shall mean process performance qualification.

(41) "Pre-Existing IP" shall have the meaning set forth in Section 11(1).

(42) "Product" shall have the meaning set forth in the Commercial Quality Agreement.

(43) "Recipient" shall have the meaning set forth in Section 16 (1).

(44) "Regulatory Approvals" shall have the meaning set forth in the Commercial Quality Agreement.

(45) "Regulatory CMC Dossier" shall mean the part of the documentation related to CMC (Chemistry, Manufacturing and Controls) information to be submitted to the authorities to support regulatory applications, including for Regulatory Approvals, relevant to the Manufacture of Product.

(46) "Regulatory Services" shall have the meaning set forth in Section 10 (9).

(47) "Release" shall have the meaning defined in Section 8(2) (a)

(48) "Representatives" shall mean any Affiliate and/or any employee, officer, director and trustee/executor of a Party and/or an Affiliate.

(49) "Rolling Forecast" shall have the meaning set forth in Section 1.2 of Annex 1.

(50) "Rules" shall have the meaning set forth in Section 16 (13).

(51) "Services" shall mean Vetter International's performance of Manufacture services or other related services for Ascendis subcontracted by Vetter International to Vetter Pharma to be performed by Vetter Pharma.

(52) "SC-Terms" shall mean the terms attached as Annex 1.

(53) "Section" shall mean a subsection of an Article.

(54) "SOPs" shall have the meaning set forth in the Commercial Quality Agreement.

(55) "Standard" shall mean, with respect to: (i) the performance of the Manufacturing, meeting the Agreed Specifications, complying with GMP (if and as applicable under the Commercial Quality Agreement), the rules and regulations officially published and promulgated by the FDA and EMA, and applicable SOPs; and (ii) the performance of the Regulatory Services, complying with the rules and regulations officially published and promulgated by the FDA and EMA.

(56) "Term" shall have the meaning set forth in Section 14(1).

(57) "Territory" shall mean [***] under consideration of Ascendis' obligations as stipulated in Section 2 (3) in case Ascendis wants to market Product in countries with quality requirements deviating from the Standard.

(58) "Vetter Competitor" shall have the meaning set forth in Section 10 (7).

(59) "Vetter International" shall have the meaning set forth first above.

(60) "Vetter Materials" shall have the meaning set forth in the Commercial Quality Agreement.

(61) "Vetter Pharma" shall mean *Vetter Pharma-Fertigung GmbH & Co. KG*, a company duly organized and existing under the laws of *Germany*, having its principal place of business at *Schützenstraße 87, 88212 Ravensburg, Germany*, the parent company of Vetter International.

(62) "Warehouse" shall mean the warehousing facility of Vetter Pharma located at [***].

ARTICLE 2: MANUFACTURE AND GOVERNANCE

(1) *Performance*. Vetter International shall supply the Product (covering PPQ and subsequent batches of Product for commercial use) to Ascendis in accordance with the terms of this Agreement, it being understood and agreed that the Manufacture of the Product shall be subcontracted by Vetter International to Vetter Pharma and be performed by Vetter Pharma, all as set forth and more fully described in the Commercial Quality Agreement. Upon Ascendis' request Vetter International shall cause Vetter Pharma to perform additional services (e.g. services referring to ongoing stability, reference materials).

(2) *Manufacture*. Vetter International shall cause Vetter Pharma to Manufacture the Product and provide the respective batch documentation in accordance with the Standard.

(3) *Quality requirements deviating from the Standard.* In case Ascendis wants to market Product in Territory countries with quality requirements deviating from the Standard ([***]), the Parties will have good faith discussions about how to deal with any additional or different country-specific rules and regulations, if any. Ascendis shall [***]. Ascendis shall regularly and in a timely manner inform and keep informed Vetter International and its Affiliates of any such additional or different country rules and regulations applicable to the Product.

(4) *Equipment*. Vetter International shall cause Vetter Pharma to procure the Equipment as listed in Annex 3 which Equipment shall be [***] Ascendis. Such Equipment, including Equipment purchased under previous agreements but used in the commercial manufacture of Product, shall be [***]. Vetter shall maintain such Equipment [***] and operate the Equipment in accordance with the SOPs. [***] for repairs and replacement, unless [***]. Vetter shall [***] maintain, and if necessary, repair or replace, all other equipment needed for the manufacture of Product.

(5) *Project Management*. A Joint Project Steering Committee ("JPSC") shall be formed comprising up to [***] members, including at least [***], from each party. If possible, meetings of the JPSC shall be aligned with [***]. As needed, the JPSC shall meet [***] to discuss and evaluate the mutual cooperation and in good faith negotiate and decide upon any issues. Meetings may be held as teleconferences, with the intention to have [***] JPSC face-to-face meeting per [***]. Each party may call for an ad hoc JPSC teleconference as deemed necessary. [***] The members of the JPSC shall attempt to amicably settle and in good faith resolve any dispute in connection with this Agreement and [***].

ARTICLE 3: MATERIALS

(1) *Delivery of Ascendis Materials*. Ascendis shall supply and deliver or have delivered to the Warehouse [***] (Incoterms 2010), free of charge and at the risk of Ascendis, including with respect to any applicable transport insurance, such quantity of the Ascendis Materials as required to properly undertake the necessary preparations for the Manufacture of the Product and to timely fulfill Purchase Orders, all in accordance with the Commercial Quality Agreement. Such delivery shall include quality certificates for the Ascendis Materials as set forth in the Commercial Quality Agreement, upon which certificates Vetter International and/or its Representatives may fully rely without further investigation. Delivery of Ascendis Materials shall take place according to the timelines specified in the SC Terms. Ascendis may deliver Ascendis Materials (e.g. API) up to [***] earlier than required according to the forecast.

(2) *Storage.* Vetter International shall store Ascendis Materials at Vetter International's Warehouse under conditions as specified in the Commercial Quality Agreement, and including such security measures as emergency power supply, temperature alarms, and backup freezer capacity. [***]

(3) *Status*. The Ascendis Materials shall at all times remain the property of Ascendis. Ascendis shall be and remain responsible and liable for the Ascendis Materials and the quality thereof. Ascendis may, in its sole discretion, provide adequate property insurance for the Ascendis Materials (whether or not included as part of the Product or otherwise), and for all shipment and storage of any thereof, in an amount and on terms satisfactory to Ascendis. [***] In the event that Ascendis chooses to insure Ascendis Materials and Product while in the custody of Vetter International, Vetter International agrees to provide Ascendis' insurance company with adequate information regarding its facilities, procedures, SOP's etc.

(4) *Information*. Ascendis shall provide any and all information with respect to the Ascendis Materials, including, without limitation, all chemical, pharmaceutical and/or biopharmaceutical compositions thereof and, to the extent reasonably known, any impact and interaction thereof on all other materials to be used in the Manufacture of the Product. If the provision of any such information has the effect, including any result of having to take additional security or safety precautions, of increasing the costs in performing obligations under the Commercial Quality Agreement or hereunder, Vetter International shall inform Ascendis thereof. Ascendis shall specifically inform Vetter International if the Ascendis Materials require any special handling or processing. Ascendis shall meet all notice and information requirements set forth herein and in the Commercial Quality Agreement, it being understood and agreed that neither Vetter International nor any of its Representatives shall have any responsibility or liability, including for lack of information or if such information should not be proper for the Manufacture, if the Product has been Manufactured in accordance with the Standard.

(5) *Delay due to Ascendis Materials*. In the event of a delay in the Manufacture of the Product arising from inadequate delivery of the Ascendis Materials (whether such delay is based on inadequacy of quality, quantity or otherwise) Vetter International may postpone the Delivery Date until such other date that Vetter International may reasonably determine in its sole discretion, after good faith consultation of Ascendis, taking into account such factors as Facility capacity, other production commitments and similar business factors, provided, however, that Vetter International shall use reasonable efforts to meet the agreed Delivery Date.

(6) *Testing*. All Vetter Materials and all Ascendis Materials shall be tested in accordance with the Commercial Quality Agreement. [***]

(7) *Use*. The Ascendis Materials shall be used for the Manufacture of the Product only. Vetter International shall notify Ascendis in writing of any surplus of the Ascendis Materials and any such surplus shall, if not usable for the Manufacture of the Product, be disposed of, returned to Ascendis or otherwise handled, all as reasonably directed by and at the cost and/or expense of Ascendis. Upon written request of Ascendis, Vetter International shall provide Ascendis with copies of a computerized inventory list, generated in accordance with the SOPs in respect of the Ascendis Materials stored at the Facility, all as separately agreed by and between the Parties in writing.

(8) *Vetter Materials*. Vetter International shall cause Vetter Pharma to source the Vetter Materials in volumes sufficient and in due time to meet Ascendis' Rolling Forecast and Purchase Orders (according to Annex 1 "SC-Terms").

ARTICLE 4: BATCH SIZE AND YIELD

(1) *Batch size.* Product shall be Manufactured in validated batch sizes. It is expected that the initial PPQ will validate a nominal batch size range of [***] DCCs and that a nominal batch size of up to [***] DCCs will be validated at a later time. Nominal batch sizes up to [***] DCCs shall be termed "Small Scale" and nominal batch sizes of [***] DCCs shall be termed "Large Scale".

(2) *Yield*. The Parties acknowledge that the Manufacturing process will yield a lower number of DCCs for Delivery than the nominal batch size. After the Manufacture of [***] Small Scale Product batches, the Parties shall evaluate and mutually agree in writing on acceptable yield targets, taking into account normal fixed and flexible losses, including, for example, [***]. Until agreement on such yield provisions has been reached, Ascendis shall pay the full batch price regardless of the yield, except in case of Vetter International's [***] (for clarity, the latter as limited by the provisions of Art. 6 (7) of this Agreement). Subsequent batches delivered in amounts below the yield targets for the Small Scale shall result in a correspondingly reduced batch price. If manufacturing in the Large Scale ([***] DCCs) is later validated, the parties shall mutually agree on acceptable yield targets for Large Scale Batches.

ARTICLE 5: INSPECTION & ACCEPTANCE

(1) *Inspection*. Ascendis shall inspect the Product according to the provisions of the Commercial Quality Agreement, and review the batch documentation without delay, but in no event later than [***] after submission to Ascendis. If the Product should not pass such inspection and/or the batch documentation should not pass such review, Ascendis shall promptly notify Vetter International in writing. If the Product has been shipped from the Warehouse to Ascendis or a third party designated by Ascendis, Ascendis shall, in accordance with the instructions of Vetter International, either return the rejected batch to the Facility or dispose of the Product.

(2) *Acceptance. Any Product and/or batch documentation not rejected as in the preceding Section* described shall be deemed accepted and approved by Ascendis to the extent that either thereof may contain a latent defect. Any Product and/or batch documentation containing a latent defect shall be deemed accepted and approved, unless rejected by written notice to Vetter International before [***]; provided, however, that in case of discovery of a latent defect, [***] that such defect has been caused solely by Vetter International before risk transfer to Ascendis. Ascendis shall notify Vetter International in writing promptly after the discovery of any latent defect. Latent defects include defects which could not, by their nature or by their low relative occurrence, be identified upon initial inspection using GMP statistical sampling techniques.

(3) *Standard*. Except for those Deviations of which Ascendis will be notified in writing as set forth in the Commercial Quality Agreement, all Product made available to Ascendis for delivery in accordance with Section 8(1) under this Agreement shall have been Manufactured in accordance with the Standard; [***].

ARTICLE 6: NON-CONFORMANCE, LOSSES AND RESUPPLY

(1) *Primary packaging materials.* Other than as set out in the Sections below regarding Non-Conforming Product, neither Vetter nor any of its Representatives shall have any responsibility or liability for any materials manufactured or supplied to the Facility by Ascendis or any third party (including Ascendis Materials and Vetter Materials) or any testing or other services performed by any third party or to undertake any testing or to otherwise certify the Vetter Materials other than as set forth in the Commercial Quality Agreement; provided, however, Vetter International shall transfer or cause to transfer to Ascendis any warranties as received in respect of primary packaging Vetter Materials and assist Ascendis to execute any such warranty claim. [***]

(2) *Vetter International's responsibility for Non-Conforming Product.* If the Parties agree about the Non-Conformance of a Product or it is otherwise concluded that Product is Non-Conforming, and the Non-Conformance is caused by

a) [***] by Vetter International or its Representatives, or,

b) the [***], including the [***]

Vetter International shall as soon as reasonably possible at Ascendis' discretion either [***] or Manufacture a replacement batch [***]. In such a case Vetter International shall additionally be obliged to [***]

(3) *Ascendis' or third parties' responsibility for Non-Conforming Product.* If Non-Conforming Product is caused by

a) Vetter Materials other than the [***], or

b) Ascendis Materials including API, or

c) any activity or instruction of Ascendis, or

d) any activity or fault of a third party, including with respect to any testing or other services performed by any third party (except for the logistic and warehousing operations to be performed by an independent subcontractor), and such Non-Conformance is not due to the [***] acts or omissions by Vetter International,

Vetter International shall as soon as reasonably possible at Ascendis' request, Manufacture a replacement batch [***] in which case [***]. In such cases, Ascendis shall [***] except for the first batch of Non-Conforming Product connected with a particular defect in which case Ascendis shall [***].

(4) *Notification of Non-Conformance.* Non-Conforming Product shall be notified by Ascendis within [***] after shipment to Ascendis or a third party designated by Ascendis, otherwise Product shall be deemed accepted, unless Non-Conformance is latent and could not have been found within [***]. Such latent Non-Conformances shall be notified by Ascendis before [***], provided however, that in case of discovery of a latent Non-Conformance, [***] that such Non-Conformance has been caused solely by Vetter International before risk transfer to Ascendis.

(5) *Delivery of replacement Products.* Vetter International shall, if Ascendis so requests, deliver replacement Product and the corresponding batch documentation within i) [***] of the Product having been determined to be Non-Conforming, or (ii) [***] after Vetter International having access to the Ascendis Materials required to Manufacture the replacement Product, whichever is later. For the purposes of any replacement, Ascendis shall supply or have supplied, as set forth in Article 3, Vetter International with the necessary Ascendis Materials.

(6) *API loss during storage.* Vetter International and/or any of its Representatives shall [***].

(7) *API loss in conjunction with the Manufacturing of Product batches.* For loss of API in conjunction with the Manufacturing of Product batches, Vetter International shall compensate Ascendis in connection with Non-Conforming Product caused by [***] up to the following liability caps:

a) in case of [***]

aa) and for any API loss occurring in connection with the first [***] Product batches Manufactured under this Agreement:

Vetter International's compensation obligation shall not exceed [***];

bb) and for any subsequent API loss:

Vetter International's compensation obligation shall not exceed [***],

provided however, in both aforementioned cases of [***] aa) and bb) above, the aggregate amount of compensation [***] shall in no event exceed [***] for all API losses under this Agreement.

b) in case of Vetter International's [***]

aa) and for any API loss occurring in connection with the first [***] Product batches Manufactured under this Agreement:

Vetter International's compensation obligation shall not exceed [***]

bb) and for any subsequent API loss:

Vetter International's compensation obligation shall not exceed [***],

provided however, in both aforementioned cases of [***] aa) and bb) above, the aggregate amount of compensation [***] shall in no event exceed [***] for all API losses under this Agreement.

For the avoidance of doubt, any compensation payments to be paid or already paid [***] for API loss caused by Vetter International's and/or any of its Representatives' [***] shall be deducted from further compensation obligations for API loss [***] caused by Vetter International's and/or any of its Representatives' [***] and vice versa with the effect that Vetter International's aggregate [***] compensation obligation [***] for any API loss caused by [***] shall in no event exceed the aggregate [***] cap as stipulated for [***] in this Article above.

Also for the avoidance of doubt, compensation for API loss within the limitations of liability agreed herein is [***] (or [***]) in cases where Non-Conforming Product is caused by 1) [***]; or 2) the [***] including the [***].

ARTICLE 7: CAPACITY AGREEMENT, FORECAST AND PURCHASE ORDERS

The Parties agree to the Capacity Agreement attached as Annex 5 to this Agreement. Forecast and Purchase Order provisions are governed by the SC-Terms attached as Annex 1.

ARTICLE 8: RELEASE AND DELIVERY

(1) *Samples for external analysis.* No later than [***] prior to the agreed Delivery Date, Vetter International shall send samples to third parties for analysis, as designated by Ascendis and further detailed in the Commercial Quality Agreement.

(2) *Release.* Product shall be released in two steps:

a) "Release" by Vetter International according to the Standard and against the "Agreed Specifications", as defined in the Commercial Quality Agreement, and

b) "Final Release" by Ascendis after (i) review of the Release documentation required to be submitted from Vetter International to Ascendis no later [***] before the Delivery Date as further detailed in the Commercial Quality Agreement, and (ii) review of results from inspections and analyses performed by third parties.

(3) *Delivery.* Product shall be delivered [***] ([***] Incoterms® 2010). Provided Ascendis has met its obligations regarding delivery of Ascendis Materials (in particular delivery in due time and in sufficient amounts as set forth in Article 3), and Vetter has met its obligations to submit Release documentation in due time, Vetter shall deliver Released Product on the Delivery Date.

(4) *Storage of Released Product.* Unless otherwise agreed between the Parties, if Product is not collected by Ascendis within [***] after notification of Product Release, Vetter International shall store such Product [***] and in accordance with its SOPs as specified in section 1.18 of the SC-Terms. The Parties agree, that storage of Products, starting from the Delivery Date, will be [***], for clarity meaning that [***]. Upon Ascendis' request Vetter International shall [***] store Released Product for up to [***], in which case, [***] [***]

(5) *Assistance.* In amplification of the provisions with respect to [***] ([***] Incoterms® 2010) set forth or referred to above, and not in limitation thereof, Vetter International shall directly or indirectly through its Representatives, upon request of Ascendis and in any event at [***], assist in (i) [***]; (ii) [***]; (iii) [***]; and/or (iv) [***]. Ascendis shall, upon request of Vetter International, provide information required for taxation or reporting purposes in respect of [***].

(6) *Shipment.* Product may only be shipped after Final Release, except under quarantine. Vetter shall coordinate all shipments with Ascendis' Logistics function. [***]

(7) *Quarantine shipment*. Product not yet Final Released may be shipped under quarantine upon prior written request of Ascendis [***]. Quarantine shipment shall not imply Ascendis' automatic acceptance of a batch, [***].

(8) *Delay in delivery*. Vetter International agrees to inform Ascendis no later than [***] after it has become apparent that the delivery of Product may be delayed. In such case Vetter International must inform Ascendis of its plan to solve the issues causing a delay, [***] to solve the issues and confirm a new Delivery Date to Ascendis as soon as possible.

ARTICLE 9: PRICES AND PAYMENTS

(1) *Prices*. Ascendis shall pay to Vetter International such prices for the Product as determined in Annex 2, plus any applicable taxes (e.g. VAT), customs, fees and other duties, if any. [***]

(2) *Price adjustments.* Vetter International may reasonably adjust its prices to reflect an increase in the costs resulting from Product specific changes (e.g. a change in the Agreed Specifications) [***]. For all other price adjustments [***].

(3) *Payments*. Without undue delay, Vetter International shall issue an invoice upon [***] or, in case of Product not yet Final Released, Vetter International shall be entitled to invoice [***]. Payments shall be made in Euros and due [***] of the invoice date (receipt of readily available funds by Vetter International). If Ascendis pays later than [***] of receipt of the invoice, Vetter International shall be entitled to interest of the invoiced amount of [***] (except when payment is subject to a good-faith resolution of any dispute). Ascendis shall add such interest, accumulated in accordance with this Article as of the time of payment due, to the invoiced amount and include such with the payment by Ascendis.

ARTICLE 10: APPROVALS, AUDITS, CHANGES AND REGULATORY SERVICES

(1) *Product*. Ascendis shall obtain and maintain, at its cost and risk, all Regulatory Approvals for the Manufacture of the Product. Ascendis shall not distribute or otherwise use the Product without first securing such Regulatory Approvals. Vetter International shall cooperate and make every reasonable effort, [***], in having information and other assistance provided as Ascendis may reasonably request with respect to the Regulatory Approvals.

(2) *Facility*. Vetter International shall cause Vetter Pharma to obtain and maintain the necessary manufacturing authorization with respect to the Facility issued by the applicable *German* health authority in accordance with the *German Medical Act (Arzneimittelgesetz)* and, upon written request

of Ascendis, Vetter International shall make available a copy of such authorization. Ascendis understands and agrees that certain regulatory authorities may still have to approve of the Manufacture of the Product, [***], and that neither Vetter International nor any of its Affiliates warrants to Ascendis any such approval.

(3) *Regulatory Services*. Ascendis shall employ Vetter International and/or its Affiliates in preparing such regulatory filings in accordance with the provisions of the Commercial Quality Agreement and this Agreement as specified in Annex 6 of this Agreement in particular by preparation of certain sections of the Regulatory CMC Dossier which are relevant to the Manufacture and provide certain supporting documents if reasonably required, all as agreed upon by the Parties in the Agreed Specifications and [***] ("Regulatory Services"). Prior to delivering Regulatory Services, Vetter International or Vetter Pharma shall, on a case by case basis, inform Ascendis in writing [***]. The Parties agree that Vetter International may employ its Affiliates, in particular Vetter Pharma, for assisting Ascendis with regard to the Regulatory Services.

(4) *Information.* If Ascendis requires Vetter International to perform Regulatory Services pertaining to any specific legislation, rules, regulations and practices or requirements of regulatory authorities and governmental bodies within the Territory (other than the generally applicable regulatory requirements of BfArM, EMA and FDA), Ascendis shall inform Vetter International and Vetter Pharma of the same.

(5) *Contact.* Ascendis shall be solely liable for all documentation, submissions and communication with governmental, health and regulatory authorities or agencies, relating to the Product and the Regulatory Approvals. Ascendis shall keep the documentation submitted to such governmental and regulatory bodies updated as required by law, applicable regulation and regulatory practices. Neither Vetter International nor any of its Representatives shall have any right or obligation to communicate with any such governmental, health and regulatory bodies regarding the Product unless required to do so by law, the Commercial Quality Agreement or as otherwise requested by Ascendis in writing.

(6) *Assistance.* Any assistance requested by Ascendis and provided by Vetter International or its Affiliates beyond the Regulatory Services in connection with regulatory submissions and Regulatory Approvals for the Products, shall be subject to the Parties' prior written agreement and the costs of the provision of such assistance shall be borne as mutually agreed by the Parties in writing. Any request for such assistance by Ascendis shall include complete instructions and any other information reasonably necessary for Vetter International to evaluate the required assistance and to calculate costs which would be incurred in performing the same in order for the Parties to discuss and agree upon the terms of the provision of such assistance.

(7) *Audits.* Ascendis may conduct routine and for-cause audits according to the provisions in the Commercial Quality Agreement. During such audits Ascendis may be accompanied by potential business and/or licensing partners subject to reasonable prior notice to Vetter International, except if such partners or any of their affiliates are [***] ("Vetter Competitor").

(8) *Extended Access to Facility.* In case of major and/or critical technical and/or quality related issues, Vetter International shall allow [***] Ascendis [***] access to its Facility as necessary to observe Manufacturing and review documents related to the GMP system and Ascendis Product batches; provided, however, Ascendis shall notify Vetter International at least [***] in advance of such request, unless this would conflict with a planned visit by a third party or internal meeting, in which case Vetter International may postpone such request by Ascendis by up to [***]. Vetter International shall provide the visiting Ascendis [***] with reasonable office space during regular working hours according to the internal procedures of Vetter International. The visiting Ascendis [***] shall comply with any and all confidentiality, security, safety, quality or similar guidelines that apply to persons present in the Facility and that are communicated by Vetter International or Vetter Pharma.

(9) *Costs for audits*. Any costs and/or expenses associated with any audits performed by any regulatory authority with respect to the Facility, the Manufacture and/or the Product shall be borne by [***], except costs incurred from audits by the *German* health authorities, FDA and/or EMA not directly related to the Product which shall be borne by [***].

(10) *Post-approval changes.* Unless mandated by compulsory regulatory changes, the JPSC shall agree upon significant post-approval changes. [***] shall bear the costs for post-approval changes (e.g. [***]) implemented [***] whereas [***] shall compensate [***] for costs of implementing [***] post approval changes (e.g. [***]). If not expressly governed by this Agreement, any impact of other changes related to prices or other terms of this Agreement shall be negotiated in good faith and agreed upon in the JPSC.

(11) *Change Control*. Any and all changes shall be processed in accordance with the change control procedures set forth in the Commercial Quality Agreement, subject to this Section and the succeeding Section. With respect to any change to be made in accordance with the Commercial Quality Agreement, Vetter International and Ascendis shall also mutually agree on any necessary or desired amendments to this Agreement, including, without limitation, price adjustments and compensation for any additional costs, efforts and/or expenses.

(12) *Changes Dispute*. In the event of a dispute regarding a change, Ascendis and Vetter International shall discuss in good faith how to proceed; provided, however, Vetter International shall not be required to cause Vetter Pharma to continue the Manufacture of the Product, which may be [***] if Vetter International and Vetter Pharma [***]. If Vetter International and Vetter Pharma [***] such incorporation or non-incorporation of a change [***], then Vetter International shall cause Vetter Pharma to continue the Manufacture of the Product with the incorporation or the non-incorporation of such change, in which event [***].

ARTICLE 11: INTELLECTUAL PROPERTY

(1) *Pre-Existing*. Except as granted under this Agreement, either Party and/or any of its Representatives shall not acquire any right, title or interest in any and all intellectual property, including any patent, trademark, copyright, industrial design, trade secret, know-how and any other intellectual property, whether patentable, registered or otherwise (individually and collectively, "IP") of the other Party and/or any of its Representatives. Any right, title or interest in and to such IP existing prior to the Effective Date (respectively, "Pre-Existing IP") shall not in any way be affected by this Agreement.

(2) *[***]*. Any [***] solely in respect of the API ("API Invention") shall be [***]. Ascendis shall [***] disclosed to Vetter International and/or any of its Representatives and [***] ("Ascendis Disclosed Manufacture IP").

(3) *[***]*. Any [***] in respect of the Manufacture including [***] ("Manufacture Invention"), shall be [***].

(4) *Licenses*. Vetter International and/or any of its Affiliates shall during the Term of this Agreement grant Ascendis, subject to the terms of this Agreement, a [***]. Ascendis shall during the Term of this Agreement grant Vetter International and/or its Affiliates a [***]. Only to the limited extent as may be necessary to enable Vetter International to [***], Ascendis shall grant Vetter International and/or any of its Affiliates a [***] under

(i) [***], and

(ii) [***],

in both cases (i) and (ii) for [***].

(5) *Infringement*. [***] shall [***] of any third party claim that the Ascendis Materials, any Information of Ascendis, other matter provided by Ascendis, or the use [***] of any thereof, infringes any IP of any third party. [***] shall [***] of any third party claim that any manufacturing process owned and used hereunder [***] infringes any IP of any third party under the patent or intellectual property laws of the *United States of America* and/or the *European Union* or any member state thereof [***].

ARTICLE 12: LIABILITY, INDEMNIFICATION, INSURANCE AND RECALL

(1) *Liability.* Except as expressly set forth in this Agreement, Vetter International and/or any of its Representatives [***] which liability is limited as follows:

a) in case of [***]

aa) and claims connected to one of the first [***] Product batches Manufactured under this Agreement:

Vetter International's aggregate liability [***], or

bb) and claims connected to any subsequent Product batch:

Vetter International's aggregate liability [***].

b) in case of [***]

aa) and claims connected to one of the first [***] Product batches Manufactured under this Agreement:

Vetter International's aggregate liability [***], or

bb) and claims connected to any subsequent Product batch:

Vetter International's aggregate liability [***].

For clarity, aforementioned liability caps [***].

For the avoidance of doubt, any compensation payments to be paid or already paid [***] based on [***] under this Section shall be deducted from further compensation obligations for Costs and Liabilities [***] with the effect that Vetter International's aggregate [***] compensation obligation [***] for Costs and Liabilities [***] shall in no event exceed the aggregate [***] cap as stipulated in this Section [***].

Vetter International and/or any of its Representatives [***] as long as each follows the standard manufacturing, storage and other practices used in the German pharmaceutical contract manufacturing industry in performing its respective obligations which means, among other things, that each may rely on the correctness and completeness of the Agreed Specifications, the Information of Ascendis and/or any other information or direction by or on behalf of Ascendis.

(2) *Indemnification*. [***].

(3) *Procedure*. Each Party shall promptly notify the other Party in writing of any claim, suit or other action brought or threatened in connection with or under this Agreement and shall provide reasonable cooperation in the defense of any thereof. Each Party shall not settle or otherwise resolve any such claim, suit or other action without prior written consent of the other Party.

(4) *Insurance.* Ascendis shall self-insure or maintain product liability insurance coverage with a reputable international insurance company, of at least [***] per each calendar year during the Term. Vetter International shall maintain and shall cause Vetter Pharma to maintain product liability insurance coverage (to the extent commercially reasonable and practicable and if otherwise, Vetter International shall remain responsible and liable for such coverage herein set forth) with a reputable insurance company, in the aggregate of [***] per each calendar year during the Term, with [***]. Upon request of the other Party, each Party shall provide reasonable documentation and certificates to confirm that such insurance coverage is in effect.

(5) *Recall Costs.* If any Product is recalled and such recall (for clarity, which must not be for Ascendis' convenience) has solely been caused by [***] shall be liable to compensate [***] direct costs of recall, which liability is limited as follows:

a) in case [***]

aa) and a recall connected to one of the first [***] Product batches Manufactured under this Agreement:

Vetter International's liability is limited to a maximum of [***] in aggregate per recall, or

bb) and a recall connected to any subsequent Product batch:

Vetter International's liability is limited to a maximum of [***] in aggregate per recall,

b) in case [***]

aa) and a recall connected to one of the first [***] Product batches Manufactured under this Agreement:

Vetter International's liability is limited to a maximum of [***] in aggregate per recall, or

bb) and a recall connected to any subsequent Product batch:

Vetter International's liability is limited to a maximum of [***] in aggregate per recall.

For clarity, aforementioned liability caps shall not apply in case of [***]. Any loss of API caused in connection with a recall shall be compensated in accordance with the provisions in Section 6 (7) above.

(6) For clarity, Vetter International and/or any of its Representatives shall have no warranty obligation (in German *Gewährleistungsverpflichtung*), responsibility or liability to Ascendis (or any third party on behalf of Ascendis) for any loss of the Ascendis Materials, Product liability, recall or otherwise beyond what is expressly stipulated in this Agreement.

ARTICLE 13: LIMITATIONS

(1) *Special Damages*. Notwithstanding anything to the contrary contained in this Agreement, neither Party nor any of its Representatives shall be responsible or liable to the other Party and/or any of its Representatives for any reason whatsoever (even upon the occurrence of a tort with respect to the Product or otherwise) for loss of profits (except any profits contained in the prices to which Vetter International may be entitled for completion of its contractual obligations), loss of good will, loss of business or special, incidental, indirect, exemplary or consequential damages, except if any of the foregoing arises out of [***] a breach of the confidentiality provisions contained in Article 16 of this Agreement and in any case subject to the liability limitation as stipulated in [***].

(2) *No Warranty*. Except as in this Agreement expressly set forth, Ascendis agrees that neither Vetter International nor any of its Representatives makes or has made any other representation, warranty, covenant or agreement (whether express or implied). Any representation, warranty, covenant or agreement set forth in this Agreement is exclusive and in lieu of any other warranties, written or oral, direct, implied or statutory, including, but not limited to, express or implied warranties for merchantability, quality or fitness for a particular purpose.

(3) *No Liability*. Notwithstanding anything to the contrary contained in this Agreement, it is expressly agreed by and between the Parties that no Representative of Vetter International shall assume any responsibility or liability , but Vetter International shall be responsible and liable for the performance of any of its Representatives to the same extent as if Vetter International had performed or failed to perform, all as contemplated or required hereunder, and any claim made under this Agreement (for clarity, specifically including the Commercial Quality Agreement) shall exclusively be made against Vetter International.

ARTICLE 14: TERM AND TERMINATION

(1) *Term*. This Agreement shall be in full force and effect for an initial term of five (5) years, commencing as of the date of first regulatory approval (market authorization) of Ascendis' TransCon hGH product ("Initial Term"). Ascendis shall notify Vetter in writing of the date of first regulatory approval no later than [***] after having obtained such. Upon the expiration of the Initial Term and any subsequent term, this Agreement shall automatically be renewed for subsequent terms of two (2) years each (Initial Term and any subsequent term collectively, the "Term"). For clarity, any rights or obligations accrued prior to the expiration of the Term or termination of this Agreement (respectively, the "Completion Date") shall not prejudice or preclude any remedies either Party may have under this Agreement.

(2) *Termination*. Neither Party may terminate this Agreement without cause, [***] and with (earliest) effect from two (2) years after expiry of the Initial Term

(3) *Termination for cause.* Each Party (as applicable) shall have the right to terminate this Agreement (with immediate effect or, if applicable, after the expiration of an applicable time period) upon prior written notice if the other Party is in major default in the fulfillment of any material obligation under this Agreement. The term "major default" shall include, but not be limited to (i) insolvency, bankruptcy, liquidation, or appointment of a receiver of any significant part of the property, of a Party and/or Vetter Pharma; (ii) in the case of any other default which can be cured, the failure to commence to remedy the default during a period of ninety (90) calendar days after the giving of written notice specifying such default; and (iii) in respect of Ascendis, the failure to self-insure or provide for or maintain product liability insurance as required under this Agreement, or pay any insurance premiums when due; (iv)failure to establish mutual agreement in accordance with Section 10(12) within forty five (45) calendar days.

(4) *Specific termination right for cause by Ascendis.* Ascendis shall have a specific termination right for cause (with immediate effect) in case Vetter International and/or Vetter Pharma [***] are being taken over by a competitor of Ascendis (for clarity, meaning [***]).

(5) *Specific termination right for cause by Vetter International.* Vetter International shall have a specific termination right for cause (with immediate effect) in case Ascendis is being taken over by a Vetter Competitor.

(6) *Consequences*. Upon the Completion Date, Vetter International shall, in its sole discretion, sell to Ascendis and Ascendis shall purchase, at the prices herein provided, any Product for which Purchase Orders have been or are required to be placed in accordance with the SC-Terms on or prior to the Completion Date and, at the purchase prices thereof, all Vetter Materials and other materials ordered as contemplated in or permitted under this Agreement. Ascendis shall be responsible and liable to Vetter International for any amounts related to, based upon or arising out of such termination, including for an orderly cessation of the Manufacture and any related activities, as well as such other amounts accruing prior to the Completion Date; provided, however, it is agreed and understood by Vetter International that any and all expenditures scheduled under the Manufacture not actually made due to such termination shall be deducted from any of the foregoing amounts. Upon the Completion Date, Vetter International shall arrange for delivery to Ascendis, or destruction, of any Ascendis Materials at the Facility, [***]. Upon the Completion Date, Vetter International shall make available, as is and where is, to Ascendis [***]. Vetter International shall have returned to Ascendis all documentation (including copies thereof) constituting Information of Ascendis; provided, however, notwithstanding the foregoing, Vetter International or any of its Affiliates may retain such limited quantity of the Product, the Ascendis Materials (all thereof sufficient for [***]) and such documentation as may be necessary for proper record keeping in satisfaction of legal requirements. Upon the Completion Date, Ascendis shall return to Vetter International any and all documentation (including copies thereof) provided to Ascendis and constituting Confidential Information of Vetter International and/or any of its Affiliates; provided, however, Ascendis may retain such limited number thereof as may be necessary for proper record keeping in satisfaction of legal requirements.

(7) *Survival.* Articles [***] shall survive the Completion Date.

ARTICLE 15: ANTI-BRIBERY AND DATA PROTECTION

(1) *Anti-Bribery.* The Parties shall comply at all times with all applicable laws and regulations in particular with such combating bribery and corruption ("Anti-Bribery Laws"). The Parties hereby represent and warrant that they have not offered to pay, paid, or accepted, and undertake that they will not offer, pay, or accept, any bribes (including any improper gifts or entertainment) to or by any person (including, in particular, any government or public official of any jurisdiction) to secure or retain a business advantage for the benefit of Vetter International and/or Ascendis under or in connection with this Agreement.

(2) *Policies and Procedures.* The Parties shall take appropriate steps, in particular maintain and effectively enforce internal policies and procedures, to ensure that the Parties' Representatives, agents, or any other person acting on behalf of the Parties will not breach any Anti-Bribery Laws. The Parties shall be responsible for any breach of Anti-Bribery Laws by its Representatives, agents, or any other person acting on behalf of the Parties under or in connection with this Agreement.

Each Party represents and warrants to notify the other Party without delay, if in connection with this Agreement

a. one Party discovers a violation of applicable anticorruption and antitrust laws which are relevant for the performance of this Agreement; or

b. investigations against one Party have been initiated by public authorities.

(3) *Data Protection.* Each Party shall comply with all applicable laws, statutes, regulations relating to personal data protection.

ARTICLE 16: CONFIDENTIALITY

(1) The confidentiality provisions of this Article shall govern Confidential Information (as defined below) disclosed in connection with this Agreement in every respect.

(2) "Confidential Information" means any proprietary information, samples, technical data, trade secrets or know-how, including, but not limited to, research and product plans, products, services, lists of collaborators and corporate partners, markets, developments, inventions, processes, including manufacturing processes and procedures and processes as may be embodied or evidenced in formulae, manufacturing data, specifications and other related documents, patents and patented designs, copyrights, trademarks, industrial design, improvements, discoveries, ideas, devices, writings, any intellectual property and proprietary information relating to a product, as well as that directly derived or resulting from any of the foregoing, and/or any information or matter that a reasonable business person would or should deem confidential or proprietary, formulas, technology, marketing, finances or other business information disclosed by either Party (the "Discloser") (either directly or indirectly in writing, orally or otherwise also during the presence at premises of a Party) to the other Party (the "Recipient") whether or not labeled "Confidential" after the Effective Date.

(3) Each Party agrees to maintain in confidence, to the same extent that it maintains its own Confidential Information secret, all Confidential Information of another Party. Except with Discloser's prior written consent, Recipient will not, during or subsequent to the term of this Agreement, use Confidential Information for any purpose whatsoever other than for the performance of this Agreement or disclose Confidential Information to any third party other than Representatives who have a need to know in order to perform the Services provided that the Recipient procures that any of such Representatives receiving Confidential Information shall be subject to and bound in writing by confidentiality obligations substantially similar to the terms set forth in this Agreement. The agreement(s) defining such obligations and binding the Representatives of the Recipient shall be provided to the Discloser by the Recipient upon request. Recipient agrees that Confidential Information shall remain the sole property of Discloser. Recipient further agrees to take all reasonable precautions to prevent any unauthorised disclosure of Confidential Information. Notwithstanding the above, Recipient's obligation under this Clause 12 relating to Confidential Information shall not apply to information which:

a. is known to Recipient at the time of disclosure to Recipient by Discloser as evidenced by written records of Recipient,

b. has become publicly known and made generally available through no wrongful act of Recipient,

c. has been received by Recipient without restriction on disclosure from a third party or

d. is independently developed by or on behalf of the Recipient other than under this Agreement and without the aid, application or use of Discloser's Confidential Information as evidenced by written documentation.

(4) Notwithstanding any provision in this Agreement to the contrary, the Recipient may disclose Confidential Information of the Discloser to the extent Recipient is required to do so by any governmental or regulatory authority or court. In such event, the Recipient shall promptly notify the Discloser when such requirement to disclose has arisen, and cooperate with Discloser so as to enable Discloser to: (i) seek an appropriate protective order; (ii) make the confidential nature of the Confidential Information known to such governmental or regulatory authority or court; and (iii) make any applicable claim of confidentiality in respect of the Confidential Information.

(5) Upon the termination of this Agreement (irrespective of the reason therefore), or upon Discloser's earlier request, Recipient will deliver on request to Discloser all of Discloser's property, including in particular that relating to Confidential Information, which is in Recipient's possession or control.

(6) Each Party acknowledges and agrees that Confidential Information may be stored on each Party's customary electronic data processing system and transmitted (sent and received) by each Party to another Party's designated electronic mail address without encryption or other protective measures, unless otherwise agreed in writing. Any electronic mail address received by each Party from another Party shall be deemed a designated address unless otherwise indicated.

(7) Each Party shall make no tangible copies or reproductions of Confidential Information of another Party unless reasonably required for the performance of this Agreement. Each Party shall ensure that any notices or marks referring to confidentiality or to proprietary rights as may be found on Confidential Information are reproduced on any and all such copies or reproductions made as hereunder permitted. Each Party agrees that it will, at the reasonable written request of another Party, destroy or otherwise dispose of all tangible records, reproductions or copies containing Confidential Information of such other Party; provided, however, that one (1) copy may be retained and stored for legal purposes. Digital backup files automatically generated by each Party's customary electronic data processing system shall not be deemed to constitute a retained copy, provided, however that no such backup files may be stored for a period exceeding [***].

(8) Except as otherwise required by law (including securities laws and regulations), neither Party will make any public announcement or press release regarding the existence or terms of this Agreement or such that mentions the other Party without the prior written consent of the other Party and the content of any such public announcement or press release shall be mutually agreed by the Parties in writing. It is specifically agreed [***]

(9) Each Party agrees to indemnify, defend and hold the other Party and/or any of its Representatives harmless from and against any and all Costs and Liabilities resulting from or arising out of breach by it and/or any of its Representatives of the provisions of this Article 16.

(10) The obligations of Recipient under this Clause 12 shall survive the Completion Date and shall remain in effect for a period of [***] from the Completion Date.

ARTICLE 17: MISCELLANEOUS

(1) *Force Majeure*. No Party shall be responsible or liable to the other Party and/or any of its Representatives, and no default shall be deemed to have occurred, for failure or delay in performing any obligations or for other non-performance if such failure, delay or other non-performance is caused by or arises from any strike, stoppage of labor, lockout or any other labor trouble, shortage of energy or raw material or any significantly prolonged inability to obtain materials or shipping space, due to the material default or significant delay by any supplier or sub-contractor or other events due to internalization of operations and services typically and customarily provided by a third party, fire, flood, lightning, fog, storm, unusual weather conditions, explosion, accident, earthquake, volcanic ash, epidemics, act of God, any public enemy, sabotage, invasion, war (declared or undeclared), riot, embargo, governmental or administrative act or restraint, prohibition on import or export of the Product or materials incorporated therein or parts thereof, or any matter or cause that is unavoidable by or beyond the reasonable control of the affected Party (each, an event of "Force Majeure"). A Party shall be under no obligation to settle a strike, labor stoppage, lockout, or any other labor trouble by entering into any agreement to settle any thereof and until any such matter is settled to the satisfaction of the affected Party, such matter shall continue to be deemed Force Majeure. Any and all of the foregoing shall also apply to a Party to the extent that an Affiliate of such Party is performing or providing any service (including under Section 15(8) referred to) or work in connection with the obligations of a Party. A Party claiming Force Majeure shall promptly notify the other Party specifying the cause and probable duration of the failure, delay or other non-performance. Neither Vetter International nor any of its Representatives shall be under any obligation to fulfill any Purchase Order which has been, or should have been scheduled to be performed during a time period of Force Majeure; provided, however, a Party so affected shall undertake every reasonable effort to fulfill its contractual obligations to the extent reasonably possible under the circumstances.

(2) *United Nations*. The *United Nations Convention on Contracts for the International Sale of Goods* shall have no application to, and shall be of no force and effect with respect to, the matters set forth or contemplated in this Agreement.

(3) *Entire Agreement*. This Agreement constitutes the entire agreement with respect to the matters set forth or contemplated in this Agreement and supersedes in any and all respects any prior communication, proposal, quotation, negotiation, conversation, discussion and agreement concerning the matters set forth or contemplated in this Agreement, and any terms and conditions thereof shall be null and void.

(4) *Conflict.* In the event of any conflict between any provision of the Commercial Quality Agreement and the other provisions of this Agreement, the provisions of the Commercial Quality Agreement shall exclusively govern and control any and all technical, pharmaceutical and/or quality related matters of the Manufacture, whereas the other provisions of this Agreement shall exclusively govern and control any other matters.

(5) *Severability*. Any provision of this Agreement held void, invalid or unenforceable shall be replaced by a mutually agreed provision that is effective, valid and enforceable and in compliance with the lawful purposes and intentions as contained in or determinable under this Agreement. Any matter not initially considered shall be resolved by incorporating such reasonable provision in order to complete this Agreement which approaches to the maximum extent such lawful purposes and intentions. The effectiveness, validity and enforceability of this Agreement shall remain independent of any provision which might be or has become void, invalid or unenforceable except if any replacement thereof is not possible and this Agreement would then not have been entered into.

(6) *Amendments*. Any amendment or modification of the provisions in this Agreement contained, specifically including this Section, shall take effect only by a written document signed and duly executed. The Appendices may be amended from time to time separately and independently of the Commercial Quality Agreement.

(7) *Assignment*. Neither this Agreement nor any right or obligation of each Party shall be assignable or transferable, except as herein provided, without the prior written consent of the other Party; provided, however, a) Vetter International may cause internal logistic and warehousing operations to be performed by an independent subcontractor (currently [***]) and Vetter International shall be and remain responsible and liable for any performance of or failure to perform by such contractor and b) Ascendis may assign its business related to the Product to [***].

(8) *Legal Notices and other communication*. Any and all legal notices, requests, demands and other communication hereunder shall be in English (and any and all costs and/or expenses associated with necessary translation shall be borne by the incurring Party), be addressed as follows, or to such other address or fax number as each Party may specify in a notice pursuant to this Section, and be deemed duly given upon receipt if and when such receipt is on a Business Day and during normal business hours of the recipient or otherwise on the then-succeeding Business Day, and if mailed by registered or certified mail, return receipt requested (and for greater certainty, be deemed unduly given if delivered by email):

If to Ascendis:
Ascendis Pharma A/S
Attn.: Legal Counsel
Tuborg Boulevard 12
D-2900 Hellerup, Denmark

If to Vetter International:
Vetter Pharma International GmbH
Attn. Managing Director
Eywiesenstraße 5,
D-88212 Ravensburg, Germany

With copy to:
Vetter Pharma-Fertigung GmbH & Co. KG
Attn. Head of Legal Department
Schützenstraße 87,
D-88212 Ravensburg, Germany

The Parties agree that documents such as forecasts, Purchase Orders, changes orders, etc. may be submitted by e-mail.

(9) *Interpretation*. The headlines of the Articles and the Sections are for convenience of reference only and shall not affect the interpretation of this Agreement. Any understanding or interpretation of any legal term contained or referred to in this Agreement shall solely be defined and interpreted in accordance with the laws of *[***]*, irrespective of any other meanings or interpretations under any other source or body of law as may be found applicable to this Agreement by any court that may claim or assess jurisdiction under any conflict-of-laws provisions or otherwise, any of which other meanings or interpretations shall have no application to and be of no force and effect with respect to the matters herein set forth, referred to or contemplated.

(10) *Independent Parties*. Each Party and any of its Affiliates are independent parties and nothing in this Agreement is intended or shall be deemed to create a partnership, a joint venture or a relationship of an agent with its client or an employer with its employee. No Party or any of its Affiliates shall have authority to make any statements, press releases, representations or commitments of any kind, or take any action which shall be binding on the other Party and/or any of its Affiliates, except as may be expressly authorized in writing which authorization shall not be unreasonably withheld.

(11) *Timely Performance*. Any failure by either Party to request performance or non-performance by the other Party and/or any of its Affiliates or to claim a breach of this Agreement shall neither be construed as a waiver of any right under this Agreement nor affect any subsequent failure to request performance or non-performance or claim a breach, nor affect the effectiveness, validity and enforceability of this Agreement or any part thereof nor prejudice or preclude such Party with respect to any subsequent action. Any request for performance or non-performance by either Party and/or any of its Affiliates or claim of a breach of this Agreement, including breach of this Section, shall be effective, valid and enforceable only if such request or claim is reduced to writing.

(12) *Dispute Resolution, Governing Law*. The Parties shall attempt to amicably settle and in good faith resolve any dispute in connection with this Agreement, by negotiations between designated representatives prior to resorting to any court action. If no amicable settlement and good faith resolution thereof has been achieved within [***], such dispute may be brought by written notice to the executive management representatives who shall use reasonable endeavors to amicably settle and in good faith resolve such dispute within [***] of receipt of said notice. If such settlement fails, either Party may, at its sole discretion, refer any dispute, controversy or claim arising out of or in connection with this Agreement to Arbitration under [***] ("Rules").

All disputes, controversies or claims arising out of or in connection with the present Agreement shall be finally settled in accordance with the Rules by [***] appointed in accordance with the Rules. The seat of arbitration shall be [***]. The language to be used in the arbitral proceedings shall be English. Annexes to any procedural document may also be provided in the German language.

This Agreement including the Commercial Quality Agreement and all Annexes and Appendices thereto shall be governed by, construed and interpreted, and all disputes, controversies or claims arising under or in connection with this Agreement shall be resolved in accordance with the substantive law of [***] without recourse to any conflict of laws rules. The arbitral tribunal shall have the authority to order production of documents only in accordance and within the limits of [***] as current on the date of this Agreement.

Any decision or arbitral award delivered in the arbitration shall be reasoned and in writing, and shall be final and binding on the Parties and enforceable in any competent court of law. The Parties undertake to comply promptly with any award without delay and shall be deemed to have waived their right to any form of recourse insofar as such waiver can validly be made. The existence and content of the arbitral proceedings and any rulings or award shall be kept confidential by the Parties and members of the arbitral tribunal except to the extent that disclosure may be required of a Party to fulfill a legal duty, protect or pursue a legal right, or enforce an award before a state court or other judicial authority. Notwithstanding, before making such information public, the interested Party shall notify the other(s), in writing, and shall afford them a reasonable opportunity to protect their interests if they deem it necessary.

The losing party shall bear the costs of the arbitration, pro rata, if applicable.

(Page remainder left blank intentionally, immediately followed by signature page.)

IN WITNESS WHEREOF, duly authorized representatives of each Party have executed this Agreement on the days and year at the places below written.

ASCENDIS PHARMA A/S

__Hellerup_____ *(place)*, dated this ____14th____ day of ____December__ *(month)*, 2018_____

*(signed)*__/s/ [***]_____

Name: [***]

Title: [***]
Ascendis Pharma A/S

VETTER PHARMA INTERNATIONAL GMBH

Ravensburg, Germany, dated this ____10th__day of ____December_____ *(month)*, 2018____

*(signed)*___/s/ [***]_____ *(signed)*__/s/ [***]_____

Name:__[***]_____ Name:__[***]_____

Title:__[***]_____ Title:__[***]
[***]

ANNEX 1: SC-TERMS

In relation to all communications specified below, emails to appointed Logistics contact persons at both Ascendis and Vetter shall be deemed acceptable.

1.1	LONG RANGE FORECAST	Ascendis Pharma shall provide a good faith estimate of total annual volumes of [***] rolling. The first [***] are covered with the “Rolling Forecast”. The Long Range Forecast shall to be send to Vetter [***]. The Long Range Forecast is non-binding and only for planning purposes. Significant forecast changes shall be indicated to Vetter as soon as they are known to Ascendis Pharma and need to be discussed together.
1.2	ROLLING FORECAST	[***] rolling forecast has to be provided by the Ascendis Pharma and sent to Vetter [***]. The forecast must be starting [***] the forecast is provided. The forecast must include requested volumes indicated with number of units per presentation and requested delivery months or dates on the following product group basis: • [***] [***] The Rolling Forecast is split into “Binding period” and “Flexible Period” as described in section 1.3 and 1.5. Shall, in any [***], a Rolling Forecast not be provided in time by Ascendis Pharma, the Demand applicable for the subsequent [***] shall be determined by Vetter on the average quantities of [***] as set forth in the previous Rolling Forecast, i.e. the Demand applicable for [***] in which a Rolling Forecast has not been provided shall be [***]. [***] of the Rolling Forecast shall be deemed as a non-binding planning period.
1.3	BINDING PERIOD	[***] of each Rolling Forecast shall be deemed as a binding period (“Binding Period”). With every new Rolling Forecast, duly signed and authorized Purchase Orders shall be provided for [***]. In [***] of the Binding Zone, a Purchase Order change [***]. [***]

1.4	PURCHASE ORDERS	A Purchase Order (or PO line) must be placed for [***], specifying the presentation strength ([***]), the requested batch size ([***]) and the requested Delivery Date [***].
1.5	FLEXIBLE PERIOD	[***] of each Rolling Forecast are considered as Flexible Period. [***], which becomes part of the Flexible Period, will be used to build-up the “Annual Reference Quantity”.
1.6	DEFINED RANGES IN THE FLEXIBLE PERIOD - COMMERCIAL	**[***] Variances in the Flexible Period** To steer [***] Forecast volumes, the following variance will be checked (no reconciliation will be done) [***]. Flexible Period ([***]): Aggregated volumes/batches per presentation of the new forecast ([***]) compared to the previous forecast ([***]) can have a variance of [***] Vetter is not obliged to produce forecasted volumes above this defined range. Any and all forecasted Demand increases outside of the Binding Period or above the defined range (Maximum Quantity), must be approved by Vetter in writing. The Parties shall in good faith (no issue if sufficient capacity is available) discuss options for increased Demand. If forecasted volumes are below the defined range, Vetter will indicate this to Ascendis Pharma. Within an annual reconciliation, the annual variance will be verified as described in section 1.10 and 1.12.
1.7	ANNUAL REFERENCE QUANTITY	**Annual Reference Quantity** In order to commonly steer the annual volumes, assure the right production capacity and to make an annual reconciliation, an Annual Reference Quantity is set through [***]. The Annual Reference Quantity will be build-up [***] by taking the last [***] as stated in the following example: [***]
1.8	ANNUAL MAXIMUM QUANTITY - COMMERCIAL	The maximum quantity covered through this agreement is as listed below: [***] Vetter is not obligated to produce forecasted volumes above this defined range. Any and all forecasted Demand increases outside of the defined range (Maximum Quantity) must be approved by Vetter in writing. The Parties shall in good faith (no issue if sufficient capacity is available) discuss options for increased Demand.

1.9	ANNUAL MINIMUM QUANTITY - COMMERCIAL	The minimum quantity covered through this agreement is as listed below: [***] If forecasted volumes are below the defined range, Vetter will indicate this to Ascendis Pharma.
1.10	ANNUAL RECONCILIATION	Ascendis Pharma and Vetter will [***] compare the “Annual Reference Quantity” with the “Actual Ordered Quantity” meaning the actual ordered quantity for (visual inspected product) by Ascendis Pharma. This is called “Annual Reconciliation. The following sections 1.3, 1.5, 1.8, and 1.9 define the agreed quantities on a yearly variance as well as possible consequences of non-orders or forecast changes.
1.11	MARKET-LAUNCH PHASE	Each Party understands that short-term Demand can fluctuate significantly during the period of market launch of the Product for a particular country or countries of the Territory as separately agreed in writing. **Definition Launch Phase** Such period shall commence upon receipt of the first marketing authorization for the Product granted by [***] and expire [***], unless otherwise in good faith discussions mutually agreed upon (“Market Launch Phase”). [***] prior to the anticipated grant of such authorization, Ascendis Pharma shall provide the best figures possible of its anticipated Demand for units of the Product for the then following [***]. During the **Flexible Period**, aggregated volumes of the new Rolling Forecast ([***]) compared to the previous Rolling Forecast ([***]) may be reduced by up to [***]. On [***] during the launch phase, the Rolling Forecast has to be updated. [***] **Variances for Binding and Flexible Period** To steer [***] Forecast volumes, the following variances will be checked (no reconciliation will be done) [***]: **Binding Period** ([***]): Aggregated volumes of the new forecast ([***]) can have a variance of [***]

Flexible Period ([***]): Aggregated volumes of the new forecast ([***]) compared to the previous forecast ([***]) can have a variance of [***]

Annual Reference Quantity

As described in section 1.7

Annual Reconciliation

As described in section 1.10

Annual Maximum / Minimum Quantities

During the launch phase, [***]. The maximum annual quantity covered through this agreement is as listed below:

- Maximum: [***]
- Minimum: [***]

Vetter is not obliged to produce forecasted volumes above this defined range. If forecasted volumes are below the defined range, Vetter will indicate this to the Ascendis Pharma to guide yearly volumes.

[***]

Compensation Annual Reconciliation

Compensation fees during the launch period are calculated as described in 1.12 “Compensation Payments” [***]

For the Binding Zone during the launch phase the compensation fee for a cancelled batch is [***].

For the Flexible Zone during the launch phase the compensation fee for a cancelled batch is [***].

In case of postponement or cancellation on Ascendis Pharma’s own responsibility, the SCM terms used for Commercial Supply will be valid.

1.12 COMPENSATION PAYMENTS

Vetter will always have a good faith discussion based on the current capacity situation.

If Vetter can use the filling slot with another order, compensation fees do not apply.

If an order cancellation occurs during the **Binding Period** (filling slot cannot be used with another order), the following compensation payments apply:

[***]

In case of an annual forecast reduction outside of the agreed ranges for the Annual Reconciliation (less than the annual Minimum Quantity), the following compensation payments apply:

[***]

Please also see separate FC-Reconciliation Calculation Model

1.13	ROLLING FORECAST AND PURCHASE ORDER CONFIRMATION	Vetter will send the order confirmation in [***] due to the internal planning cycle which [***].
1.14	FREEDOM OF FILLING DAY	Ascendis Pharma issues orders and forecasts based on the requested delivery date. Vetter confirms and invoices against the confirmed delivery date. There is no obligation for Vetter to provide an exact filling day with the forecast or any order tracking tool. Vetter has the flexibility in filling days. Vetter will always try to prioritize orders with critical shelf life. [***]
1.15	ARRIVAL OF API/ EXCIPIENTS/ MATERIAL/ DOCUMENTS	If Ascendis has not already delivered API in sufficient quantity to the Warehouse, Vetter will order the API for confirmed orders from Ascendis Pharma at least [***]. Ascendis Pharma will send an API delivery date confirmation within [***], upon which Vetter can rely. The API must be released for manufacturing at Vetter minimum [***]. The API shall be delivered [***]. Receipt of materials can be rejected if not delivered in accordance with the Quality Agreement. If this results in the loss of a filling slot, it will be considered as a cancellation and treated with possible compensation. In case of apparent delay of API delivery, Ascendis will inform Vetter [***]. A mutual decision whether to postpone the manufacturing date will be done minimum [***], otherwise a cancellation fee will be applied. [***]
1.16	MATERIAL INVENTORY	Vetter Materials will be ordered based on the provided Purchase Orders and rolling forecasts as well as the specified [***]. It moreover includes the required minimum quantities which have to be purchased depending on the component suppliers. If demand is dropping significantly or an agreed specification change is performed, [***].
1.17	[***]	In addition to [***], Vetter will source and keep [***]. Additional [***] can be commonly agreed upon and will be recommended for [***].

1.18	PICK UP FINISHED GOODS	After Vetter Release of the product, the forwarder has to [***] to reserve a pick-up slot at Vetter. Vetter grants Ascendis Pharma [***] storage after the confirmed delivery date or Vetter batch Release (latest date counts). For a later pick up after this [***] period, storage fees will be invoiced ([***]).
1.19	INVOICING/ PAYMENT TERMS	Already mentioned in Term Sheet
1.20	CUSTOMS/ IMPORT/ EXPORT	Vetter Logistic Service Center has to be noticed at least [***] in advance of arrival of goods. In case of tri-angular arrangements, the customs invoice has to be provided at least [***] in advance. In case Vetter will be the importer of the API, real API value has to be stated on the import documents according to German Law. Vetter cannot provide assistance without this information. IMPORTANT NOTICE In case the delivery of the API to Vetter will be from [***], Ascendis Pharma will inform Vetter [***] in advance and the following points will have to be clarified: • [***] Only after clarification of these points, it will be clear whether and under which conditions Vetter may act as an importer. If during the importing function by Vetter, any deviation, conflicts or custom issue/costs (e.g. [***]) may arise, [***].
1.21	[***]	The supply of [***] is currently not within the scope of the project. However, Vetter is open to offer an evaluation of this service if requested from Ascendis Pharma. During the implementation of a [***] at Vetter, the term sheet has to be checked and if needed adapted before the planned revision cycle.
1.22	KPIs	KPI´s have to be discussed between Ascendis Pharma and Vetter. Vetter and Ascendis Pharma will create a set of manufacturing KPI’s tracking the ordering process for quantity and delivery time fulfillment. Those KPI’s will mutually be tracked and presented during the business review meeting. If irregularities or challenges will be identified, actions will be commonly defined during the business review meeting (BRM).
1.23	REVISION	The points 1.1 – 1.22 will be mutually discussed and revised during the business review meeting (BRM) latest after completing [***].

Example Forecasting Model (Annual Reference QTY)

[***]

ANNEX 2: PRICES

PRICING with assumptions

Performance Profile for Commercial Supply
[***]

Price Estimates for Commercial Supply:

[***]

Additional: Procurement and Assembly of [***]

- **[***]**

ANNEX 3: EQUIPMENT

Equipment at Vetter owned by Ascendis Pharma:

[***]

—CONFIDENTIAL—

Annex X to the Supply Agreement

COMMERCIAL QUALITY AGREEMENT

for

the Manufacture of pre-filled application systems

by and between

ASCENDIS PHARMA A/S

and

VETTER PHARMA-FERTIGUNG GMBH & CO. KG

—CONFIDENTIAL—

TABLE OF CONTENTS

THIS COMMERCIAL QUALITY AGREEMENT ("CQA") taking effect on the Effective Date, by and between Ascendis Pharma A/S, duly organized and existing under the laws of Denmark and having its place of business located at Tuborg Boulevard 5, 2900 Hellerup, Denmark ("Ascendis"), and Vetter Pharma-Fertigung GmbH & Co. KG, duly organized and existing under the laws of Germany, having its place of business at Schützenstraße 87, 88212 Ravensburg, Germany ("Vetter Pharma"), and Ascendis and Vetter Pharma individually also a "Party" and collectively the "Parties",

W I T N E S S E T H:

WHEREAS, this CQA is made as an integral part of the Supply Agreement and attached thereto as Annex X; and

WHEREAS, certain activities concerning to the Manufacture of the Product have been subcontracted by Vetter to Vetter Pharma;

WHEREAS, such Manufacturing shall be performed by Vetter Pharma as set forth and more fully described in this CQA; and

WHEREAS, this CQA outlines the technical and pharmaceutical responsibilities of Ascendis and Vetter Pharma with respect to the quality of the Product;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements hereinafter set forth, and subject to the terms and conditions of this CQA, Ascendis and Vetter Pharma agree as follows:

ARTICLE 1: DEFINITIONS

For all purposes of this CQA and all amendments hereto, the following capitalized terms, whether used in the singular or plural, shall have the same and uniform meanings as below defined and specified, unless the context otherwise requires. Capitalized terms not defined in this CQA shall have the meaning specified in the Supply Agreement where referenced.

(1) "Affiliate" shall have the meaning as set forth in the Supply Agreement.

(2) "Agreed Specifications" shall have such meaning as defined in Section 4(2), written documentation of which shall be set forth in Appendix 4.

(3) "API" shall mean actice pharmaceutical ingredient as specified in Appendix 2 of this CQA.

(4) "Appendix" shall mean an appendix attached to this CQA.

(5) "Article" shall mean an article of this CQA.

(6) "Ascendis" shall have the meaning set forth first above.

(7) "Ascendis Materials" shall mean the materials provided by Ascendis as listed in the Agreed Specifications.

(8) "Business Day" shall have the meaning as set forth in the Supply Agreement.

(9) “Complaint” shall have the meaning set forth in Article 14(1).

(10) “Confidential Information” shall have the meaning as set forth in the Supply Agreement.

(11) “Critical Deviations” shall have the meaning set forth in Article 12(1).

(12) “Supply Agreement” shall mean the supply agreement by and between Ascendis and Vetter.

(13) “Deviations” shall have the meaning set forth in Article 12(1).

(14) “CQA” shall mean this commercial quality agreement and its Appendices.

(15) “Effective Date” shall have the meaning as set forth in the Supply Agreement.

(16) “EMA” shall have the meaning as set forth in the Supply Agreement.

(17) “Facility” shall have the meaning as set forth in the Supply Agreement.

(18) “FDA” shall have the meaning as set forth in the Supply Agreement.

(19) “GMP” means the Good Manufacturing Practices issued and officially published by the FDA and the current Good Manufacturing Practices issued and officially published by the European Commission and in the latter case adopted by German law, which are applicable to the Manufacture of the Product; provided, however, that such GMP to the extent that they are Product related and/or Product-specific shall have been provided by Customer to Vetter Pharma.

(20) “Information of Ascendis” shall have such meaning as defined in Section 4(1), written documentation of which shall be set forth in Appendix 2.

(21) “Major Deviations” shall have the meaning set forth in Article 12(1).

(22) “Manufacture” or “Manufacturing” shall mean the operations of Vetter Pharma and/or its Affiliates to manufacture the Products, specified in Appendix 2, for and on behalf of Ascendis at the Facility, including but not limited to production, processing, filling, lyophilization, labeling, packaging, storage and testing of the Product, materials and intermediates, receipt of materials (including Ascendis Materials and Vetter Materials), as well as related in-process control, quality control testing, quality assurance and certification activities, the generation of stability data of Product, as the case may be; all operations as detailed in the Agreed Specifications.

(23) “Minor Deviations” shall have the meaning set forth in Article 12 (1).

(24) “Out-of-Specification (OOS) Result” – All test results that fall outside the specifications

(25) “Party” and “Parties” shall have the meanings set forth first above.

(26) “Product” shall mean, for the purpose of this CQA, such product listed in Appendix 2 containing API or a placebo.

(27) “Regulatory Approvals” shall mean any and all approvals, consents, clearances, permissions, licenses and registrations to be obtained and maintained from the applicable authorities by Ascendis in accordance with the Territory laws in order to Manufacture, use (including but not limited to the use in clinical trials), register, import, export, distribute, market, promote and/or sell, the Product.

(28) “Regulatory Services” shall have the meaning as set forth in the Supply Agreement.

(29) “Response Period” shall have the meaning set forth in Article 11(3).

(30) “SOPs” shall mean the standard operating procedures of Vetter Pharma, applicable to the Product and its Manufacture hereunder.

(31) “Territory” shall have the meaning as set forth in the Supply Agreement.

(32) “Vetter International” shall have the meaning as set forth in the Supply Agreement.

(33) “Vetter Pharma” shall have the meaning set forth first above.

(34) “Vetter Materials” shall mean the materials provided by Vetter Pharma as listed in the Agreed Specifications except Ascendis Materials.

ARTICLE 2: TECHNICAL AND PHARMACEUTICAL RESPONSIBILITIES

(1) Delineation. The technical and pharmaceutical responsibilities of Ascendis and Vetter Pharma with respect to the quality of the Product are as listed and set forth in Appendix 7.

(2) Contacts. Ascendis and Vetter Pharma shall agree to appoint employees to act as contact persons, as listed in Appendix 6, for all Manufacture and Product quality related aspects.

(3) Regulatory. Ascendis shall be responsible for the Regulatory Approvals whereas Vetter Pharma shall obtain and maintain the German manufacturing authorization (in German, Herstellerlaubnis) with respect to the Facility.

(4) Third Parties. Vetter Pharma agrees not to subcontract any of its Manufacture obligations without prior written consent of Ascendis. Any approved subcontractor shall be listed in Appendix 8.

ARTICLE 3: MATERIALS

(1) Ascendis shall provide to Vetter Pharma the Ascendis Materials together with manufacturers’ quality certificates, other data, documentation and information as may be required by law, applicable regulatory authorities or as Vetter Pharma may reasonably request. In respect to the Ascendis Materials, Vetter Pharma shall perform an incoming inspection in accordance with the Agreed Specifications. If Ascendis requests in writing import of the Ascendis Materials from a country outside of the European Union, and if notified at least [***] prior to each and every import, Vetter Pharma shall act as the importer of record for the Ascendis Materials. Ascendis ensures that any facility where the API is or has been manufactured, tested, (re-) packaged, processed, labelled, shipped, stored, delivered and/or transported prior to the handover at the Facility, has been inspected and is under regulatory supervision of the applicable competent regulatory authorities, including, but not limited to the EMA. Ascendis shall provide sufficient documentation to demonstrate any of the foregoing and will keep Vetter Pharma informed about all information with regards to such facility, any changes thereof and any incident or observations related to the activities performed therein or that may have an impact on the Ascendis Materials and/or Vetter Pharma’s risk assessment, including information of any regulatory inspections results. To fulfill the legal obligations of Vetter Pharma, Ascendis shall procure that a quality representative of Vetter Pharma shall have the right to audit the production of API. Vetter Pharma can request Ascendis to perform the audit on behalf of Vetter Pharma.

(2) Vetter Pharma shall furnish the Vetter Materials as well as all labour, materials and equipment that are necessary to perform the Manufacture other than the Ascendis Materials. The Vetter Materials shall be sampled according to the SOPs, and inspected and tested in accordance with the Agreed Specifications, it being understood and agreed that such testing shall be performed according to validated test methods on qualified and calibrated equipment if such testing should be required. Upon completion of the inspection and testing, such Vetter Materials may be used for the Manufacture of the Product.

(3) Vetter Pharma shall perform such inspection or testing as in this Article 3 provided and any additional inspection or testing shall be subject to the prior written agreement between the Parties.

(4) The Ascendis Materials and the Vetter Materials, and the processes associated with Manufacturing of the Product, shall be evaluated by Vetter Pharma in accordance with Appendix 5, to prevent cross contamination and to ensure compliance with [***]. New products or materials that are introduced into the Facility will be evaluated by Vetter Pharma in accordance with Article 11 below. On the basis of pharmacological and/or toxicological data of each new product introduced to the Facility, health based exposure limits shall be calculated, as required under the applicable EU GMP guidelines and Directives, and an evaluation and specification of measures for the manufacturing of the new product shall be performed. New products and materials introduced into the Facility will be processed and stored in compliance with SOPs, and GMP. Vetter Pharma shall submit a change request for review and approval by Ascendis in accordance with Article 11 below, if any new product or material, which is outside of the matrix of existing products, will be introduced into the Facility, and if the equipment used for the manufacturing or processing of the new product or material will also be used for the Manufacturing or processing of the Product. Vetter Pharma [***]. For all new products introduced to the Facility, a risk assessment shall be performed on the basis of their pharmacological and/or toxicological properties, and suitable measures (e.g. containment) for the manufacturing of the new products shall be specified.

ARTICLE 4: INFORMATION AND SPECIFICATIONS

(1) Ascendis shall keep Vetter Pharma informed of (i) any Product-specific requirements, and (ii) any legislation, rules and regulations as well as practices of any regulatory authority other than GMP, which may affect the Product and/or the Manufacture and Ascendis shall specifically inform Vetter Pharma of the effect of any thereof, including any changes to either thereof, which changes shall be subject to the change control procedures herein and in the Supply Agreement set forth. Ascendis shall provide all such information, including its manufacturing and handling specifications, information about potency of the API and the Product, testing procedures and other technical information concerning the Manufacture of the Product, handling and processing of Vetter Materials and Ascendis Materials (the “Information of Ascendis”), which Information shall be set forth in Appendix 3.

(2) Ascendis and Vetter Pharma shall mutually agree upon the product specifications, including such part of the Information of Ascendis relevant for the Manufacture of the Product at the Facility (the “Agreed Specifications”), written documentation of which shall be set forth in Appendix 3 and 4 and be signed by duly authorized representatives of Ascendis and Vetter Pharma. Ascendis shall ensure that the Agreed Specifications comply with the Regulatory Approvals and the Information of Ascendis as set forth in Appendix 5.

(3) Changes to the Agreed Specifications requested by Vetter Pharma or Ascendis shall be subject to the change control procedures herein and in the Supply Agreement set forth, it being understood and agreed that any changes to the Agreed Specifications shall be approved by Ascendis and Vetter Pharma in writing prior to implementation.

ARTICLE 5: MANUFACTURING

(1) Vetter Pharma agrees to Manufacture the Product in accordance with the Agreed Specifications, the SOPs, GMP and as described in Appendix 7.

(2) Ascendis shall provide Product-specific technical support as required.

(3) Ascendis may, subject to the Regulatory Approvals, use the Product in clinical trials provided such Product conforms to the Agreed Specifications, GMP and the requirements.

ARTICLE 6: INSPECTION AND TESTING OF THE PRODUCTS

(1) Release Testing. Prior to delivery of the Product to Ascendis, [***] the Product as indicated in the Agreed Specifications and in Appendix 7.

(2) Inspection. Ascendis shall inspect all Products, including samples and documentation provided according to Article 9, after delivery as set forth in the Supply Agreement.

(3) Release. [***], in which exception event the methods of every inspection and testing repeated by Ascendis shall substantially correspond with the inspection and testing methods used by Vetter Pharma before delivery.

(4) Sterility. [***], Ascendis shall inform Vetter Pharma on any such regulatory requirements and shall [***] provide Vetter Pharma with a copy of the results of any such testing. Except as in the preceding sentence set forth, [***]

ARTICLE 7: PRODUCT SHELF-LIFE, EXPIRY DATE

Ascendis shall provide Vetter Pharma with the information necessary to identify or determine the shelf-life and expiry date as set forth in Appendix 7.

ARTICLE 8: RECORDS, DOCUMENTATION AND SAMPLING

(1) Records. The records of the documentation listed in Appendix 5 shall be maintained by Vetter Pharma for [***] or such shorter period as may be permitted by law. Vetter Pharma shall inform Ascendis prior to any destruction of such records. Ascendis may request in writing, within [***] of such notification by Vetter Pharma, that the records shall be sent to Ascendis. Should Vetter Pharma not receive such written request, such records may be destroyed.

(2) Documentation. For each batch of Product, Vetter Pharma shall provide Ascendis with the documentation set forth in Appendix 5. Upon prior written request, the records of the documentation listed in Appendix 5 shall be made available for review at the Facility, during normal business hours, by Ascendis or any applicable regulatory authority within the Territory.

(3) Sampling. Vetter Pharma shall take and keep reference and/or retained samples of each batch of Product as set forth in the Agreed Specifications. Ascendis shall notify Vetter Pharma of any additional sampling to be performed during Manufacture at Vetter Pharma, all as set forth in a mutually agreed and written sampling plan. Vetter Pharma shall have the right, but not the obligation to keep samples of each batch of Product for its own records; provided, however, the maximum amount of such samples shall not exceed the number required for [***] of the Product. If Vetter Pharma should decide to take such samples, Vetter Pharma shall inform Ascendis thereof in writing.

ARTICLE 9: RELEASE AND SHIPMENT

(1) Release. [***] Ascendis shall be responsible for and shall perform the final release of the Product for final use. No Product shall be released until Vetter Pharma has successfully performed all Manufacture, including all testing, required by the Agreed Specifications.

(2) Shipping. Ascendis to provide Vetter Pharma with a Distribution Protocol including details of any specific labeling requirements, temperature control & monitoring and Product security measures during shipping.

(3) Delivery. Ascendis to provide Vetter Pharma with an order including quantity of Product to be shipped, delivery address and contact details of recipient. Delivery of the Product and/or samples shall be in accordance with the terms and conditions set forth in the Supply Agreement.

ARTICLE 10: INSPECTION AND REGULATORY CONTACTS

(1) Inspection. Ascendis shall, upon reasonably prior request by written notice and during normal business hours, have the right to inspect, [***], such areas of the Facility used for the Manufacture. The inspection shall not exceed the duration of [***], except in the event of any critical concern with respect of the quality of the Product. Ascendis retains the right to conduct “for cause” audits at times mutually agreed upon by Ascendis and Vetter Pharma.

(2) Confidentiality. All audit teams of Ascendis, each member whereof shall explicitly be bound in writing by the confidentiality provisions of the Supply Agreement, shall at all times be accompanied by members of Vetter Pharma personnel, and not be divided into more than [***] sub-teams.

(3) Regulatory. Each Party shall inform the other Party prior to any inspection by a regulatory authority in respect of the quality of the Product and/or its Manufacture. Each Party shall submit to the other Party any reports or results received from such regulatory authority in connection with the inspection. Ascendis shall be the responsible contact for any regulatory inquiries concerning its regulatory filings and Regulatory Approvals. Vetter Pharma shall provide reasonable assistance with regard to such regulatory inquiries, provided the inquiry is related to the Manufacture of the Product at the Facility. Copies of such regulatory inquiries shall be forwarded to Vetter Pharma within [***] upon receipt by Ascendis. Ascendis shall not submit documents to any regulatory authority with respect to processes performed at the Facility without prior review of Vetter Pharma.

(4) Mutual Assistance. The Parties shall assist each other in responding to any questions or other requests from regulatory authorities with respect to the Product or the Manufacture and shall provide reasonably required information or data within adequate timelines, in no event later than requested by such regulatory authorities. Upon receipt of any such information, the Parties shall consult each other in an effort to arrive at a mutually acceptable answer to such question or request or procedure for taking other appropriate action; provided, however, that nothing contained herein shall be construed as restricting the right of either Party to make a timely report of such matter to any regulatory authority or take other action that it deems to be appropriate or required by applicable laws or regulations. Each Party shall have the right to disclose any such information to a regulatory authority within the Territory to the extent reasonably required or requested by such regulatory authority in connection with a filing, inspection or otherwise; provided, however, [***], without prior review and written approval of Vetter Pharma, all to the maximum reasonable extent while in compliance with said legal requirement.

ARTICLE 11: CHANGE CONTROL

(1) System. Vetter Pharma shall use a documented system of procedures for the control of quality related changes to Vetter Materials, Ascendis Materials, the Agreed Specifications and suppliers.

(2) Changes. Subject to and in accordance with its SOPs, Vetter Pharma will provide to Ascendis changes that require Ascendis review and approval or changes that require notification only and will implement changes that require no Ascendis involvement or notification. Any changes affecting the Product quality shall be reviewed and approved in writing by Ascendis and Vetter Pharma prior to implementation. Unless otherwise agreed in writing, Ascendis and Vetter Pharma shall respond to the other on a change request by the other within [***].

(3) Review. Ascendis shall review and shall respond to the contemplated changes and the timeline for implementation within [***] after receipt of the change notification ("Response Period") with the understanding that in urgent cases the Parties may mutually agree to a shorter timeframe. There shall be a shorter Response Period if a change is requested by a regulatory, governmental or health authority or agency or if required by applicable laws, rules or regulations, subject to required implementation timelines.

(4) Dispute. Vetter Pharma shall not unreasonably withhold its approval of changes requested by Ascendis; provided, however, Vetter Pharma may take into account such factors as capacity of the Facility, technical capability, production commitments and similar business factors. Ascendis shall not unreasonably withhold its approval of changes requested by Vetter Pharma; provided, however, Ascendis may take into account GMP, any applicable legislation, rules and regulations, and where appropriate any Information of Ascendis. Any dispute regarding a change shall be settled in accordance with the provisions of the Supply Agreement

(5) Exceptions. The following formal adaptations of the master batch record shall be excluded from the above change control process as not relevant with respect to GMP:

- correction of typing errors and grammar;
- adaptation of page and line breaks;
- adaptations of layout without changes of position numbers;
- adaptation of part designations and master batch record page header regarding pharmaceutical non-relevant information, e.g. product codes of Ascendis;
- amendments regarding information already documented in the batch record but not predefined in the Agreed Specifications, e.g. already existing definitions are multiplied such as stamping fields to document the sterilization; and/or
- replacement of alpha-numeric SOP numbers with the current five-digit SOP numbers.

(6) Requirements. Ascendis shall keep Vetter Pharma informed of (i) any legislation and any rules, regulations and practices of the regulatory authorities of any country within the Territory; and (ii) any requests of regulatory authorities of the Territory with respect to changes affecting the Manufacture of the Product, the Agreed Specifications, it being agreed that in the event such a request is made by a regulatory authority, such request shall be communicated to Vetter Pharma within [***] upon receipt by Ascendis including all necessary information to evaluate such change and its effects.

(7) Expiration. Vetter Pharma shall have no obligation to follow the above change control procedures if the Product is not Manufactured at the Facility for more than [***].

ARTICLE 12: DEVIATIONS, OOS

(1) Documentation. All Product quality related deviations ("Deviations") and OOS results shall be investigated and documented by Vetter Pharma according to SOPs. The documentation shall be retained as part of the batch documentation for the batch affected. For all confirmed OOS, for all Deviations which might affect the Agreed Specifications ("Major Deviations") and for all Deviations which have affected the Agreed Specifications ("Critical Deviations"), a complete and approved investigation report shall be sent to Ascendis upon completion of the investigation by Vetter Pharma. The foregoing shall not apply to deviations which have not affected the quality of the Product , but are not in accordance with the Agreed Specifications ("Minor Deviations").

(2) Report. If a Deviation should occur or become necessary which, after investigation by Vetter Pharma, is likely to be categorized as a Major Deviation or a Critical Deviation (including OOS), Vetter Pharma shall, within [***] from the time of discovery of either thereof, provide Ascendis with a written report setting forth preliminary information on such Deviation. Ascendis can request additional information about a Deviation, by telephone, TC or mail, from Vetter, and Ascendis can provide an assessment of the Deviation to Vetter before closure of the Deviation. Vetter Pharma will provide complete and approved investigation report upon completion of the investigation by Vetter Pharma, usually within [***] from the time of discovery of the deviation or OOS.

If a retest is necessary Vetter Pharma will submit the restest protocol to Ascendis for review and approval. The results will be reported within the investigation report.

(3) Authority. Upon the occurrence of a Major Deviation or a Critical Deviation, Ascendis shall have the final responsibility to determine the significance of the impact of said Deviation on the Product, including the further disposition of the affected Product. Ascendis shall not use any Product in humans in the event that Vetter Pharma has given the status "rejected" to such Product. Vetter Pharma shall only dispose of any Product if confirmed by Ascendis in writing.

ARTICLE 13: VALIDATION AND QUALIFICATION

(1) Validation. Solely with respect to any Product-specific and Product quality related validation and qualification of processes, packaging, analytical methods, cleaning and equipment, Ascendis and Vetter Pharma shall mutually agree upon a validation and qualification documentation to achieve compliance with GMP and the responsibilities set forth in Appendix 7.

(2) Review. Ascendis shall review and approve the Product-specific and Product quality related validation documentation within [***]. The respective documentation will be provided by Vetter Pharma to Ascendis in English.

(3) Qualification. The suppliers of Vetter Materials shall in appropriate intervals be re-qualified by Vetter Pharma as required by GMP, if and as applicable. Such re-qualification shall be performed according to the applicable Pharmacopoeia listed in the Agreed Specifications and shall include a full testing of said materials by an external laboratory or other qualified third party.

ARTICLE 14: COMPLAINTS

(1) Definition. A Complaint means any written or electronic record that claims or documents deficiencies related to the identity, quality, safety, efficacy or performance of the Product after it has been released to Ascendis.

(2) Authority. Ascendis shall have sole authority for resolving all post-release issues and inquires, including adverse events and complaints received from users, contractors or regulatory authorities regarding the Product (each, a "Complaint").

(3) Information. Ascendis shall inform and provide Vetter Pharma with information and, if available, samples, of any Complaint relating and/or affecting the Product quality that indicate that the cause could have reasonably been a result of the Manufacture at the Facility and/or of any Regulatory Services provided by Vetter Pharma.

(4) Investigation. If a Complaint could have been reasonably caused by the Manufacture at the FacilityVetter Pharma, Ascendis shall request in writing and arrange for the investigation of such Complaint by Vetter Pharma. Upon any such request, Vetter Pharma shall investigate any Complaint relating and/or affecting the Product quality as required by Ascendis, and Vetter Pharma shall provide a written report on the results of such investigation within [***]. If such investigation should exceed such period, Vetter Pharma shall notify Ascendis thereof.

(5) Adverse Impact. Vetter Pharma shall notify Ascendis within [***] if the results of an investigation relating to any other products manufactured at the Facility may, in accordance with and subject to Vetter Pharma's reasonable assessment, adversely impact the quality of the Product. Such notification shall be subject to Vetter Pharma's prior compliance with confidentiality agreements entered into with other companies or customers. If confidentiality agreements regarding other products do not permit Vetter Pharma from providing certain documentation or detail, Vetter Pharma shall provide redacted copies of documentation or a summary of the results with respect to the quality impact on the batch of the Product.

ARTICLE 15: RECALL AND REGULATORY REPORTING

(1) Recall. If any matter should be discovered and identified either potentially requiring a Product recall or the need for informing an authority related to released Product, the discovering Party shall notify the other Party promptly, in any event within [***] of discovery. If a Party should become aware of any Product allegedly or proven to be the subject of a recall, market withdrawal or correction in any country, such Party shall notify the other Party within [***].

(2) Authority. Ascendis shall be responsible to initiate and conduct Product recalls. Ascendis shall undertake any and all efforts to completely withdraw the recalled Products from any and all distribution channels or applicable markets. [***]. If Product should be subject to a recall or a potential recall as mutually anticipated by and between the Parties, Vetter Pharma shall allocate the status "rejected" to such affected Products then currently be found at the Facility.

(3) Investigation. If requested by Ascendis, Vetter Pharma shall promptly arrange for the performance of investigations and Vetter Pharma shall timely make respective investigation reports regarding the defect or cause available for regulatory reporting. All communications with the appropriate regulatory authorities shall be handled by Ascendis.

ARTICLE 16: ANNUAL PRODUCT QUALITY REVIEW

(1) Reporting Period. The annual Product quality review reporting period shall be mutually agreed upon and the final report sent to Ascendis following Ascendis request for information. Vetter Pharma shall provide the approved annual Product quality review report on a scheduled basis as agreed between Ascendis and Vetter Pharma, and provide copies of the report to Ascendis in a timely manner.

(2) Report Contents. The layout and structure of the respective report shall be according to SOPs, including but not limited to the following categories of information to be evaluated and reported:

- Listing and summary of all batches Manufactured during review period (including rejected, reworked, and reprocessed lots)
- Listing and summary of any changes pertaining to the Product and process including master batch record, Product-related processing equipment, Manufacturing area, chemical and microbiological test methods, in-process control, visual inspection, packaging materials
- Listing and summary of Major Deviations and Critical Deviations investigations including corrective and preventive actions taken
- A review of critical in-process controls and finished Product results
- Qualification status of relevant major Product-related equipment and utilities information applicable during review period
- Listing and summary of stability studies and results
- Listing and summary of quality-related complaints and recalls and the investigations then performed
- A review of the provisions of this QA to ensure up-to-date status
- Statement that *"All these data prove that the Manufacture of Product is in compliance with the current Good Manufacturing Practices as described in Parts 210/211 of Title 21 of the Code of Federal regulations and in the EU-GMP-Guides"*

ARTICLE 17: STABILITY STUDIES

If separately agreed, and according to the conditions described and agreed to as specified in an appendix to the Supply Agreement, Vetter Pharma shall execute the stability program in accordance with the mutually agreed stability protocols, including protocol preparation, sampling, storage in stability chambers, testing, reporting of results and compilation of documentation, all as provided in this CQA. The stability protocol, changes to the stability protocol and the stability report must be approved by Ascendis. Ascendis shall be responsible for final data interpretation and providing stability information to any Authority. Any stability related procedures required during the Manufacture of the Products shall be included in the Information of Ascendis and shall be incorporated into the Agreed Specifications by mutual agreement of Ascendis and Vetter Pharma.

ARTICLE 18: COMBINATION PRODUCT

(1) Any Product intended by Ascendis to be registered, marketed, sold, used and/or shipped to the United States of America shall comply with the requirements regarding combination products, as referred to and set forth in the Code of Federal Regulations (also, "CFR"). As the sponsor, it is the responsibility of Ascendis to ensure any such overall compliance. Ascendis shall have all required documents, processes and systems in place required to ensure any such compliance.

(2) Vetter Pharma shall support Ascendis in the efforts of Ascendis demonstrating Ascendis' compliance with the CFR relating to combination products, by Vetter Pharma maintaining certain procedures and systems as applicable to the Manufacture, as set forth in Appendix 5. Ascendis shall, during its regular audits, review the suitability and effectiveness of such procedures and systems.

(3) To enable Vetter Pharma to provide such assistance, Ascendis shall provide Vetter Pharma with all information required and/or reasonably requested by Vetter Pharma.

(4) In accordance with section 4.4(a) of 21 CFR Part 4, the quality requirements under the Code of Federal Regulations for co-packaged and single-entity combination products, which each of the Parties agrees is applicable to the Product, can be satisfied by Ascendis in one of two ways:

Under section 4.4(a)(1), a manufacturer can demonstrate compliance with each applicable regulation in its entirety (e.g., with all of the drug GMPs and the QS regulation, for a drug-device combination product);

Under section 4.4(a)(2), if the combination product is subject to the drug GMPs and QS regulation, these two sets of requirements can be met by demonstrating compliance with (1) either the drug GMPs or QS regulation; or (2) those provisions specified in section 4.4(b) from the other of these two sets of regulations.

(5) It is hereby agreed by and between the Parties that the Product shall be Manufactured at the Facility of Vetter Pharma in accordance with the Agreed Specifications. Ascendis shall ensure that the Specifications are and shall be in accordance with the provisions of 21 CFR Part 4, section 4.4(a)(2) and therefore comply with GMP and with the provisions of the QS regulation of 21 CFR Part 820 to the extent necessary to comply with subsection 4.4(b)(1) of 21 CFR Part 4.

ARTICLE 19: MISCELLANEOUS

(1) Term. This CQA shall become effective and shall be in force and effect for the same period as the Supply Agreement is in force and effect; provided, however, that those obligations of the Parties shall survive which, by their nature, shall survive the expiration or termination of this CQA, including on-going regulatory requirements, set forth in this CQA and, for example, maintaining records and supporting Product Complaint investigations.

(2) Integral Part. This CQA shall be an integral part of the Supply Agreement and all of the provisions set forth in of the Supply Agreement shall apply to this CQA specifically including, for the avoidance of doubt, Section 15, named Dispute.

In the event of a conflict between the terms of the Quality Agreement and the Supply Agreement, the terms of the Quality Agreement shall prevail in respect of any matters connected to all technical, pharmaceutical and/or quality related matters of the Manufacture of the product and any regulatory requirements in respect of the product. The terms of the Supply Agreement shall prevail in respect of all other matters.

(3) Appendices. Any Appendices may be amended from time to time separately from the Articles of this CQA, after which amendment Appendix 1 shall be updated accordingly. If an additional quality document should be requested, for regulatory purposes only, such document shall not constitute an amendment of this CQA and shall not affect the provisions hereunder.

(4) Disclosure. Upon prior written request with the exception during inspections, this CQA may, in accordance with applicable law, be disclosed to any applicable regulatory authority.

(Page remainder left blank intentionally, immediately followed by the signatures page.)

IN WITNESS WHEREOF, duly authorized representatives of each Party executed this CQA on the days and year at the places below written.

ASCENDIS PHARMA A/S

Hellerup, Denmark, dated this __23___ day of _____April_____ (month), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]
[***]

(signed) /s/ [***]
Name: [***]
Title: [***]

VETTER PHARMA-FERTIGUNG GMBH & CO. KG

Ravensburg, Germany, dated this __27___ day of ____April_____ (month), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

(signed) /s/ [***]
Name: [***]
Title: [***]

(signed) /s/ [***]
Name: [***]
Title: [***]

APPENDIX 1: HISTORY OF APPENDICES

Revision Number of Appendix	Effective date	Reason for revision
		First Version no revision

Approved: Ascendis

____April_____ (month) __23___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

Approved: Vetter Pharma

__April___ (month) __27___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

APPENDIX 2: PRODUCT(S)

Dual chamber cartridges [***], pre-filled with TransCon [***] hGH Drug Substance [***] and afterwards pre-filled with Water For Injection [***]

Approved: Ascendis

__April_____ (month) __23___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

Approved: Vetter Pharma

__April___ (month) __27___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

APPENDIX 3: INFORMATION of ASCENDIS

[***]

Approved: Ascendis

__April_____ (month) __23___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

Approved: Vetter Pharma

__April___ (month) __27___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

APPENDIX 4: AGREED SPECIFICATIONS AND MATERIALS

Mutually Agreed Specifications:

[***]

Approved: Ascendis

__April_____ (month) __23___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

Approved: Vetter Pharma

__April___ (month) __27___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

APPENDIX 5: RECORDS REQUIRED BY ASCENDIS

- [***]

Approved: Ascendis

__April_____ (month) __23___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

Approved: Vetter Pharma

__April___ (month) __27___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

APPENDIX 6: CONTACT PERSONS

Ascendis Pharma A/S
Tuborg Boulevard 5
DK-2900 Hellerup
Denmark

Primary Contacts: [***]

[***]

[***]

Vetter Pharma-Fertigung GmbH & Co. KG
Schützenstraße 87, 88212
Ravensburg, Germany

[***]

Primary Contacts: [***]

Approved: Ascendis

__April_____ (month) __23___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

Approved: Vetter Pharma

__April___ (month) __27___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

[***]

[***]

APPENDIX 7: DELINEATION OF RESPONSIBILITIES (3/3)

[***]

Approved: Ascendis

__April_____ (month) __23___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

Approved: Vetter Pharma

__April___ (month) __27___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

APPENDIX 8: THIRD PARTY SUBCONTRACTORS OF USED BY VETTER PHARMA

Third Party suppliers used by Vetter Pharma will be listed in the agreed Specifications.

Permitted Subcontractor / Address	**Contracted service**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Approved: Ascendis

__April_____ (month) __23___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

Approved: Vetter Pharma

__April___ (month) __27___ (day), 2018

(signed) /s/ [***]
Name: [***]
Title: [***]

ANNEX 5: CAPACITY AGREEMENT

- Capacity commitment within binding and flexible forecast period detailed in Annex 1 “SC-Terms”
- Ascendis has the option to secure capacity beyond the [***] rolling forecast horizon through the following mechanism:
    - Upon signing the Agreement, Ascendis commits to purchasing at least [***], and Vetter commits to reserving sufficient manufacturing capacity to deliver at least [***].
    - Starting [***], no later than [***] Ascendis may commit to a minimum purchase quantity [***], and upon acceptance, Vetter guarantees to reserve sufficient manufacturing capacity to deliver at least [***].
    - [***]
    - Compensation fee = [***]
    - Example for illustration purposes:

[***]

- In case Ascendis cancels all quantities according to the Capacity Agreement, the compensation to be paid by Ascendis shall be due within [***].
- In case Ascendis purchases less than the minimum committed quantities, [***].
- Reconciliation of the period [***] will be done at [***].
- [***]

ANNEX 6: REGULATORY SERVICES

Responsibilities	**Ascendis**	**Vetter Pharma**
[***]	[***]	[***]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

MANUFACTURING AND SUPPLY AGREEMENT

("Agreement")

between

Ascendis Pharma A/S
Tuborg Boulevard 12
2900 Hellerup
Denmark

(hereinafter referred to as "Ascendis")

and

CARBOGEN AMCIS AG
Hauptstrasse 171
CH4416 Bubendorf
Switzerland

(hereinafter referred to as "Carbogen")

(hereinafter individually referred to as "Party" and collectively as "the Parties")

APPENDICES

1. INTRODUCTION

WHEREAS:

(A) Ascendis and Carbogen entered into a Master Services Agreement dated 15 February 2010 pursuant to which Ascendis and Carbogen agreed to collaborate on the development and manufacture of linker reagents;

(B) The Parties have agreed to enter into a commercial supply partnership with the objective to ensure delivery of agreed quantities of Product of the specified quality at agreed times.

(C) The Parties have agreed to enter into this Manufacturing and Supply Agreement to set forth the general terms and conditions on which the supply of different Products and additional services will be carried out.

2. DEFINITIONS

"Agreement" shall mean this Manufacturing and Supply Agreement.

"Appendix" shall mean any Appendix as amended, dated, signed and renumbered (e.g. Appendix 1.1, 2.1, 3.1… and so forth) from time to time.

"Approved Site(s)" shall mean the facilities and premises, as stated in Appendix 1, where manufacturing, analysis, packaging and control of the Products under this Agreement shall take place.

"Background Technology" shall mean the full range of Carbogen's Intellectual Property Rights and factual knowledge in relation to [***] (i) existing on the Effective Date of this Agreement and/or (ii) licensed to, acquired or developed by Carbogen outside of this Agreement but during the term of this Agreement, which Carbogen is free to dispose of.

"Business Day(s)" shall mean any working day(s) (with the exclusion of Saturday and Sunday) on which banks are normally open in either Switzerland or Denmark, as may be applicable.

"Calendar Quarter" shall mean each three (3) successive calendar months starting on 1 January, 1 April, 1 July or 1 October, respectively.

"Calendar Year" shall mean 12 successive calendar months starting on 1 January.

"cGMP" shall mean Current Good Manufacturing Practice as defined in the EC Guidelines to Good Manufacturing Practise, Volume IV, Part 1: Medicinal Products for Human and Veterinary Use.

“Confidential Information” shall mean any proprietary information, samples, technical data, trade secrets or know-how, including, but not limited to, research and development plans, products, services, lists of collaborators and corporate partners, markets, developments, inventions, processes, formulas, technology, marketing, finances or other business information disclosed by either party (the “Discloser”) (either directly or indirectly in writing, orally or otherwise) to the other party (the “Recipient”).

“Delivery” or “**Deliver**” shall mean the transfer of Product at the point where risk and responsibility is transferred from Carbogen to Ascendis according to the agreed IncoTerms.

“Delivery Date” shall mean the date of Delivery of Product by Carbogen to Ascendis or its designee as agreed in a Purchase Order.

“Effective Date” shall mean the date on which this Agreement becomes effective in accordance with Article 15.1.

“EMA” shall mean the European Medicines Agency of the European Union.

“[***]” shall mean [***].

“FDA” shall mean the Food and Drug Administration of the United States Department of Health and Human Services.

“Final Release” shall mean the final release for delivery of Product by Ascendis or its designated representative.

“Health Authorities” or “HA” shall mean any national or international health authority including but not limited to those of the European Union, Japan, and the United States.

“Intellectual Property Rights” or “IPR” shall mean without limitation, proprietary information, Know-how, patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, inventions, copyright, industrial designs etc.

“Joint Steering Committee” or “JSC” shall have the meaning assigned to it in Article 5.1.

“Know-how” shall mean any and all present and future data concerning Ascendis, Product, and any derivatives hereof e.g., but not limited to production know-how, quality specifications, analytical data, data indicated in a DMF, patents, use-, packaging- and improvement data, which data are possessed, performed and/or developed by either Ascendis or Carbogen and/or exchanged under any secrecy agreement between the Parties or any other agreement entered into between the Parties during the negotiations prior to execution of this Agreement or during the currency of this Agreement, except for Background Technology.

“Materials” shall mean starting materials & containers as listed in Appendix 8.

"Other Services" shall mean work performed by Carbogen for Ascendis which does not relate directly to the synthesis, manufacture, analysis, quality control, labelling, packaging and Delivery of the Product. Other Services are listed in Appendix 7.

"PMDA" shall mean the Pharmaceuticals and Medical Devices Agency of Japan.

"PPQ" shall mean the Process Performance Qualification of the manufacturing process of the Product "[***]", as defined in Appendix 2, at the Approved Site(s).

"Product" shall mean Products as stated in Appendix 2.

"Purchase Order" shall mean an order submitted by Ascendis according to Section 8.4 specifying Ascendis' purchase order number, required quantities of Product and requested date of delivery.

"Purchase Price" shall mean the price agreed to be paid by Ascendis to Carbogen as set forth in Appendix 3.

"Quality Agreement" shall mean the agreement set out in Appendix 4 hereto.

"Release Documentation" shall be the documentation which Carbogen shall provide to Ascendis following Carbogen's internal release of the Product. Such documentation shall at least contain a batch summary with certificates of conformance and list of deviations. Further details on the requirements for such documentation are specified in the Quality Agreement (Appendix 4).

"Service Fee" shall mean the fee for the Services performed in connection with a Purchase Order but excluding the cost of materials and 3rd party costs.

"Services" shall mean the manufacture and Delivery of Product as set out in this Agreement and the provision of Other Services as listed in Appendix 7.

"Shelf Life" shall mean the time span between the manufacturing date and the expiry date of a batch, as approved at any given time.

"Specifications" shall mean the specifications of Products, intermediates and key raw materials as listed in Appendix 5.

"**Starting Period**" shall mean the period of time from the execution of this Agreement to [***].

"Unused Service Fee" shall mean the difference between the Service Fee connected with a Purchase Order and the costs of already performed Services in connection with that Purchase Order.

3. SUBJECT MATTER OF THE AGREEMENT

3.1. This Agreement covers the post-PPQ manufacture and supply by Carbogen of Product to Ascendis for commercial use worldwide as part of Ascendis' [***] product.

3.2. Carbogen hereby undertakes, upon Ascendis' written request, to synthesize, manufacture, analyse, quality control, label, package and Deliver the Product to Ascendis, in accordance with the terms and conditions of this Agreement; and Ascendis will from time to time place Purchase Orders for Product according to forecasts as set forth in Article 6. Operations shall take place in compliance with the Quality Agreement and at the premises listed in Appendix 1.

3.3. Carbogen also undertakes to provide Ascendis with Other Services as listed in Appendix 7 according to terms agreed on a case-by-case basis in one or more separate agreements to be included in Appendix 7.

4. OBLIGATIONS OF THE PARTIES

4.1. Ascendis hereby undertakes to purchase the Product in the quantities ordered by Ascendis from time to time and on the terms and conditions agreed upon hereunder, and Carbogen hereby undertakes to supply such Product to Ascendis pursuant to the terms of this Agreement.

4.2. Ascendis is neither bound to grant any kind of exclusivity to Carbogen under this Agreement nor to purchase certain quantities of Product from Carbogen except as a consequence of having forecasted certain quantities in accordance with the provisions of Section 8.1.

4.3. In the performance of the Services, Carbogen shall, for all processes subject to cGMP, comply with all relevant FDA, EMA and PMDA rules and regulations.

4.4. Carbogen and Ascendis shall discuss and liaise regarding the present status of the manufacturing and analysis of Product on a continuous basis. Upon Ascendis' request Carbogen shall inform Ascendis of the present status and the results obtained.

4.5. During and following the term of this Agreement, Carbogen shall make available any and all documentation regarding the Product which in Ascendis' reasonable assertion is required for (i) issue of patents and/or patent applications; (ii) regulatory filings to any regulatory body to which Ascendis may apply for registration of Product in its final presentation.

4.6. Carbogen shall, up to [***], during the term of this Agreement grant [***] Ascendis [***] access (during normal business hours and upon reasonable prior notice [***]) to visit Carbogen's premises for routine audits of facilities, equipment, procedures, records and personnel. Ascendis shall also be allowed to perform for-cause audits upon [***] notice, such reasonable causes to be defined in the Quality Agreement.

4.7. Carbogen shall during the term of this Agreement allow inspectors from Health Authorities (possibly accompanied by Ascendis staff), to perform the required inspections. Carbogen shall submit any observations relevant to the Manufacturing or Analytical Control of Products from such inspections to Ascendis without delay.

4.8. On the request of Ascendis, and upon prior notice [***] Carbogen shall allow [***] representatives from Ascendis collaboration partners such as licensees, distributors (possibly accompanied by Ascendis staff), to inspect the Approved Site(s) upon prior signed Secrecy Agreement of such collaboration partners. Such inspections will be strictly related to the manufacturing or analytical control of Products. If Products are implicated in regulatory inspection findings during audits initiated by authorities or other third parties, or if such findings are otherwise relevant for the manufacturing or analytical control of Products Carbogen shall notify Ascendis without delay.

4.9. [***]

4.10. Carbogen shall not implement any change in [***] without having obtained Ascendis' prior written approval, unless such change is mandated by regulatory changes. In either case, Carbogen shall implement the changes at [***].

4.11. Other significant post-approval changes in [***] shall be mutually agreed by the JSC and [***] the cost of implementing the changes.

4.12. The Parties agree to keep each other promptly informed of any action by, or notification or other information, which it receives (directly or indirectly) from any governmental or regulatory authority, which raises any concerns regarding the safety or efficacy of Product or any medicinal products containing Product.

5. GOVERNANCE

5.1. The Parties shall form a JSC comprising of [***] members from each Party, including at least [***].

5.2. The JSC shall meet at least [***] and shall discuss and evaluate the mutual collaboration and shall in good faith attempt to resolve any disputes in connection with the Agreement. Each Party may call for an ad hoc teleconference as such Party deems necessary. As agreed between the Parties in each case, the meetings of the JSC may be carried out by teleconference, video conference or face-to-face, as the case may be, provided however that the Parties endeavour to meet face to face at least [***].

5.3. [***]

5.4. Written minutes of JSC meetings must be made alternately by each Party and must be circulated for comments no later than [***] after each meeting.

6. COMMUNICATIONS

6.1. The Parties agree that electronic communications (email) are acceptable for exchanging forecasts, Purchase Orders, order confirmations, agendas, meeting minutes and other information of an operational nature. Legal notices shall be delivered physically by courier.

6.2. The Parties agree to each appoint a primary Logistics contact person and a primary Quality Assurance contact person.

7. MATERIALS AND SUBCONTRACTING

7.1. Carbogen shall – [***] – be responsible for sourcing Materials as required from reputable third party manufacturers. Carbogen shall notify Ascendis in writing once a manufacturer has been appointed and such manufacturer shall be an approved manufacturer of the relevant Material (as defined in Appendix 8). Carbogen shall provide Ascendis with all details and information concerning the third party manufacturer as may be required by Ascendis to comply with Applicable Law and Regulations. Once a manufacturer has been appointed as an approved manufacturer of a specific Material, Carbogen shall not appoint a replacement manufacturer or a second manufacturer of the same Material without Ascendis' prior written consent, which consent shall not be unreasonably withheld or delayed. [***] Loss of Materials due to expiry caused by lowered forecast or cancelled orders shall be at the risk of Ascendis.

7.2. Any performance of the Services by a third party manufacturer shall be subject to Ascendis' prior written approval. [***] shall be considered approved by Ascendis as of the Effective Date.

8. FORECAST AND PURCHASE ORDERS

8.1. Forecast:

Ascendis shall provide Carbogen with a written rolling forecast showing Ascendis' expected requirements for the Product "[***]" ([***]) to be Delivered under this Agreement during the following [***]. The forecast for [***] will be considered fully binding on the Parties, i.e. Ascendis commits to order and purchase the forecasted quantity and Carbogen commits to Deliver such. The forecast for [***] is [***] binding [***] and the forecast for [***] shall be considered non-binding. The first such forecast shall be supplied [***]. The forecast shall be updated [***] no later than [***].

8.2. [***] of Intermediates:

Based on the forecast for [***], Carbogen shall [***] of [***] according to [***] and plan for the timely manufacture of these intermediates in due time. Carbogen shall in due time request for Ascendis to place Purchase Orders for required quantities of [***], such Purchase Orders to be issued by Ascendis within no more than [***] of having received the request. [***] To be clear: this section only covers [***]; costs of unused materials are covered in chapter 15.4 c.

8.3. [***] binding forecasts:

Before having placed Purchase Orders, binding forecasts may [***], provided, however, that [***].

8.4. Purchase Orders:

Ascendis shall from time to time place Purchase Orders with Carbogen on the terms agreed herein. A Purchase Order shall [***]. For [***], Purchase Orders must be placed in due time for at least the quantity bound through the forecasting procedure ([***]). Ascendis may also place Purchase Orders for quantities beyond the binding forecast, and Carbogen shall use [***] to Deliver such additional quantities but shall not be obliged to do so unless Carbogen confirms the full Purchase Order. Ascendis shall on each Purchase Order specify the requested date of Delivery which shall be no earlier than [***] from submission of each Purchase Order. [***] Carbogen shall confirm such Purchase Orders in writing no later than [***] upon receipt of said Purchase Orders [***].

8.5. Cancellation of Purchase Orders

In case Ascendis cancels Purchase Orders it shall pay [***]% of all costs for raw materials consumed or purchased for such Purchase Orders, [***]% of the cost of already performed Services, and the following cancellation fees:

- [***]% of the Unused Service Fee for cancellation ³ [***] before commencement of manufacture of [***]
- [***]% of the Unused Service Fee for cancellation <[***] and ³[***] before commencement
- [***]% of the Unused Service Fee for cancellation <[***] and ³[***] before commencement
- [***]% of the Unused Service Fee for cancellation <[***] before commencement
- [***]% of the Unused Service Fee for cancellation after commencement.

9. BATCH SIZE AND CAPACITY

9.1. Linker [***] shall be manufactured and delivered in a batch size of [***]. The acceptable range and the manufacturing batch sizes for intermediates shall be reflected in Appendix 6, as updated in writing from time to time upon mutual agreement.

9.2. On the Effective Date, Carbogen guarantees ability to Deliver [***] (subject to agreed forecasting procedure and no force majeure events) using [***].

9.3. On the Effective Date, Carbogen guarantees ability to deliver up to [***] (subject to agreed forecasting procedure and no force majeure events), provided [***].

9.4. The Parties agree to mutually discuss options to secure flexibility in the supply of Product and mitigate the risk of shortages in case Ascendis' actual needs turn out lower or higher than forecasted.

10. DELIVERY AND RELEASE

10.1. Carbogen shall Deliver Product ordered under Article 8 in the quantities agreed and under the common understanding by the Parties that it is of the essence to Ascendis that Carbogen observes Delivery Dates and that Product Delivered under this Agreement is of the agreed quality and Specifications.

10.2. Carbogen bears the responsibility towards Ascendis that any required conditions for storage of the Product are fulfilled until Delivery thereof to Ascendis or its designee.

10.3. Product shall be delivered to Ascendis or its designee [***] according to Incoterms 2010 in the Master Batch Record.

10.4. Carbogen shall no later than [***] prior to the confirmed Delivery Date forward the Release Documentation for Ascendis to review. Following receipt of the Release Documentation, Final Release shall be performed by Ascendis' Qualified Person within [***], such Final Release not to be unreasonably withheld or delayed. Delivery is subject to Final Release.

10.5. During the Starting Period, the time limit of [***] stated in Section 10.4 shall be [***].

10.6. Any delay in delivery of the Product and/or Release Documentation shall be notified to Ascendis no later than [***] after the delay has become apparent to Carbogen, including a description of the cause. Carbogen shall [***] solve the issues and shall confirm a new Delivery Date to Ascendis as soon as possible.

10.7. If Ascendis finds that the Release Documentation does not comply with the Specifications or with any other requirement under this Agreement, Ascendis shall notify Carbogen in writing of Ascendis' observations with respect to the non-compliance without undue delay after receipt of such documentation, provided that failure by Ascendis to do so shall not imply any loss of rights or remedy for Ascendis under this Agreement or at law.

10.8. Carbogen shall upon Ascendis' written request store released Product for a period of [***]. Requests for storage beyond the current dedicated storage capacity are contingent upon Ascendis giving Carbogen reasonable notice. [***]

11. PURCHASE PRICE AND PAYMENT TERMS

11.1. Ascendis will pay to Carbogen the Purchase Price for Product and Other Services.

11.2. The Purchase Price for Product is listed in Appendix 3. The Purchase Price for Other Services will be agreed in separate agreements as detailed in Appendix 7.

11.3. The agreed Purchase Price for Product is based on [***] and [***]. It is agreed that the Purchase Price shall be verified [***] and adjusted accordingly if [***].

11.4. Carbogen's price for the Services [***]. If Carbogen is obligated by law to charge any value added and/or similar tax to Ascendis, Carbogen shall ensure that if such value-added and/or similar tax is applicable, that it is invoiced to Ascendis in accordance with applicable rules so as to allow Ascendis to reclaim such value-added and/or similar tax from the appropriate government authority. Neither Party is responsible for taxes on the other Party's income or the income of the other Party's personnel or subcontractors. If Ascendis is required by government regulation to withhold taxes for which Supplier is responsible, Ascendis will deduct such withholding tax from payment to Supplier and provide to Supplier a valid tax receipt in Carbogen's name. If Carbogen is exempt from such withholding taxes as a result of a tax treaty or other regime, Carbogen shall provide to Ascendis a valid tax treaty residency certificate or other tax exemption certificate at a minimum of [***] prior to payment being due.

11.5. For the avoidance of doubt, the price for the Services [***].

11.6. Carbogen shall invoice Ascendis for [***] deliveries [***] or [***], whichever event comes first. Invoicing for Other Services shall follow the agreements listed in Appendix 7.

11.7. Payments by Ascendis will be made in [***] after receipt of invoice by Ascendis. All late payments will, without further notification, be charged with interest for late payment calculated on a daily basis from the due date until full payment at the rate of [***].

12. REGULATORY COMPLIANCE AND SUPPORT

12.1. Carbogen is obligated to support global regulatory requirements and requests. Health Authority Requirements are in this context defined as direct legal requirements imposed on Ascendis where non-compliance results in loss of license to operate or financial penalties due to non-compliance in the respective region. Health Authority Requests are defined as enquires from Health Authorities with relation to regulatory submissions (including but not limited to marketing authorization applications, clinical trial applications, line extensions, variations and safety requests).

12.2. Carbogen is obligated to deliver any information/data needed to support both Health Authority Requirements and Health Authority Requests. Data should be delivered to Ascendis according to respective Health Authority Controlled Terms as applicable and where possible in structured format (in a suitable file format).

12.3. Carbogen must make available any information/documentation/data required to support regulatory requirements/requests no later than [***] following the first written enquiry from Ascendis.

12.4. Ascendis shall [***] Carbogen for regulatory support. [***]

13. NON-COMPLIANCE

13.1. If Ascendis finds that Product Delivered does not conform to the terms and conditions of this Agreement, including, without limitation, the Specifications and/or Quality Agreement and/or cGMP, Ascendis shall no later than [***] after delivery notify Carbogen hereof in writing with Ascendis' observations with respect to the non-compliance. For latent defects not detectable by inspection on supply (as defined in the Quality Agreement), Ascendis shall notify Carbogen no later than [***] after Delivery in writing.

13.2. Carbogen shall within [***] calculated from the day on which such written complaint has been received by Carbogen, inform Ascendis whether Carbogen agrees or not to the complaint filed. If such response is not given within the above-mentioned [***] it is understood that Carbogen agrees to said complaint.

13.3. In the event of a dispute as to the acceptance of a batch of Product, the Parties agree to seek an amicable settlement by way of discussions between quality assurance representatives from either Party. If the dispute is not resolved amicably within [***] from Ascendis' written notice mentioned in Article 13.1, the issue may be referred to [***].

13.4. If the Parties agree or it is otherwise concluded that Product delivered does not conform with this Agreement and non-conformity is attributable to Carbogen's proven failure, Carbogen shall on mutual agreement with Ascendis, [***]. If the defect was detected after shipment from Carbogen, Carbogen shall [***].

14. RECALL

14.1. [***] shall [***] whether and under what circumstances to require the recall of batches of Product. [***] In the event that a recall of a batch from sale is necessary [***].

15. TERM AND TERMINATION

15.1. This Agreement will come into effect on the date of last signing hereof and will continue in effect until five (5) years following first commercial launch of Ascendis' TransCon hGH pharmaceutical product (the "Initial Term").

15.2. This Agreement will continue in effect after the end of the Initial Term unless and until terminated by either Party according to the provisions for termination.

15.3. Notwithstanding any termination of this Agreement, the rights and duties of the Parties with respect to any terms, which by their nature are intended to survive termination, shall survive and continue to be enforceable, including but not limited to Articles 2, 13, 14, 15, 16, 17, 18, 22.

15.4. This Agreement may be terminated:

a) By either Party upon written notice to take effect immediately in the event of:

i) An assignment by the other Party for the benefit of creditors;

ii) The admitted insolvency of the other Party;

iii) The institution of voluntary or involuntary proceedings by or against the other Party in bankruptcy, insolvency, moratorium or for a receivership, or for a winding-up or for the dissolution or reorganization of the other Party; or

iv) The taking of any action by the other Party under an act for relief from creditors;

b) By either Party upon [***] written notice to the other Party in the event of a failure of such other Party to perform or observe a material obligation imposed by this Agreement, unless such failure is cured, or the Parties have reached agreement on a plan to achieve a cure of such failure prior to the end of such [***] period.

c) By Ascendis after the Initial Term with one (1) year's written notice, provided, that Ascendis shall [***] any unused Materials not already paid for under separate work orders, which Carbogen are unable to use for other purposes than the provision to Ascendis of Product.

d) By Carbogen after the Initial Term with four (4) years' written notice, provided Carbogen actively assists in a tech transfer to an alternate supplier [***].

e) By mutual agreement of the Parties.

15.5. This Agreement may be terminated by Ascendis upon [***] notice in the event of a change of fifty percent (50%) or more of the direct or indirect ownership of Carbogen, if such ownership goes to a third party which is materially involved in the treatment of growth related disorders in humans. Carbogen shall provide prompt written notice to Ascendis of any such change.

15.6. Termination of this Agreement, for any reason, shall not release either Party from any liability which at said time it has already incurred to the other Party, nor affect in any way the survival of any rights, duties or obligations of either Party which are stated elsewhere in this Agreement to survive said expiration or prior termination. Nothing in the immediately preceding sentence shall affect, be construed or operate as a waiver of the right of the Party aggrieved by any breach of this Agreement to be compensated for any injury or damage resulting therefrom which is incurred before or after such expiration or termination.

15.7. On the written request of Ascendis and at termination of this Agreement, Carbogen shall cease using any and all tangible Know-how, inventions and technical improvements supplied or developed hereunder and shall forward such Know-how, inventions and technical improvements, copy and original, to Ascendis together with Product manufactured. Carbogen is entitled to retain one (1) copy of such documents forwarded with respect to Know-how, inventions and technical improvements, raw materials and Product manufactured, in order for Carbogen to comply with the cGMP regulations and may not be used for any other purpose. Copies so retained shall, subject to cGMP, be destroyed no earlier than [***] after delivery. Furthermore, Carbogen may keep such copies that may have been generated by automatic back-up systems.

15.8. Upon termination Carbogen shall keep the original batch documentation for Products manufactured and/or packed by Carbogen in accordance with the obligations laid down in Appendix 4.

15.9. Upon termination Carbogen shall [***] regarding the Products manufactured and/or packed by Carbogen and [***] in relation to [***] of the Products in accordance with the obligations laid down in [***].

15.10. If the Agreement is terminated [***], [***] shall [***].

15.11. Upon termination or expiry of this Agreement and upon the written request of Ascendis, Ascendis and Carbogen will enter into a tech transfer agreement ("TTA"), under which Carbogen provides [***] to obtain continued supply of Product from an alternate supplier. The costs and expenses of such tech transfer shall be agreed upon in such TTA and shall be borne [***].

16. CONFIDENTIALITY

16.1. The Recipient will not, during or subsequent to the term of this Agreement, use Confidential Information for any purpose whatsoever other than for the performance of this Agreement or disclose Confidential Information to any third party other than employees, affiliates, subcontractors or representatives who have a need to know in order to perform the Services. The Recipient agrees that Confidential Information shall remain the sole property of the Discloser. The Recipient further agrees to take all reasonable precautions to prevent any unauthorized disclosure of Confidential Information. Notwithstanding the above, the Recipients' obligation under this Clause 14 relating to Confidential Information shall not apply to information which:

a) is known to the Recipient at the time of disclosure to the Recipient by the Discloser as evidenced by written records of the Recipient,

b) has become publicly known and made generally available through no wrongful act of the Recipient,

c) has been developed independently by or on behalf of the Recipient with no use of or reliance upon the Discloser's Confidential Information,

d) has been received by the Recipient without restriction on disclosure from a third party, or

e) Recipient can establish that it is required by law, subpoena, judgement, order or other similar form of process to disclose to a government, other public authority or third party, provided that Recipient immediately upon learning of such obligation, and prior to disclosure, if lawfully possible, notifies Discloser of such disclosure obligation and reasonably cooperates with Discloser in limiting the scope of disclosure, if lawfully possible.

16.2. Upon the termination of this Agreement (irrespective of the reason therefore), or upon the Discloser's earlier request, the Recipient will deliver on request to the Discloser all of the Discloser's Confidential Information, which is in the Recipient's possession or control with the exception of such copies as provided under Clause 15.7.

16.3. The obligations of the Recipient under this Clause 16 shall remain in effect for a period of [***] after the termination or expiry of this Agreement.

17. INTELLECTUAL PROPERTY RIGHTS

17.1. All data, information and other results arising from the performance of this Agreement by Carbogen, in any way related to the Product and developed by Carbogen alone or in concert with Ascendis and/or any third party hereunder shall [***] (including, but not limited to, inventions (patentable or not), copyright and Know-how). Any pertaining tangible material, whether original or copy, in writing, electronically generated, tape recorded or otherwise, shall be submitted to Ascendis [***] upon written request. [***] Carbogen is not entitled to use Product for any other purpose than for the performance of its services under this Agreement.

Notwithstanding above, [***]. This Agreement shall not grant or be construed as granting any rights by license or otherwise to [***].

Furthermore, [***], and [***], subject to [***].

Other than as set out specifically above. This Agreement will not transfer any rights to intellectual property in any way.

17.2. Intellectual Property Rights utilized by Carbogen for purposes of performing its obligations under this Agreement shall be listed in Appendix 9 as updated by Carbogen from time to time.

17.3. The Purchase Price paid by Ascendis to Carbogen in accordance with this Agreement, shall include payment for [***] all written, other tangible and all electronically generated material [***], including, but not limited to, copyright and designs. All such written or other material [***], and [***] shall be entitled to make all possible use of it, including, but not limited to, to publish, to transfer the incorporeal rights, to edit, and in every way to change the contents and design of the said written or electronic material [***].

17.4. Ascendis shall be (i) at liberty not to make use of the said written material; (ii) entitled to make any use whatsoever of the said written material as deemed useful for any purpose by Ascendis; (iii) entitled to make changes and/or deletions of any kind in the said written material and/or to transfer and/or assign its rights to same. The Parties hereto confirm that remuneration based on commercial sale of the said written material, according principles for such sales and copyrights to software are not relevant for this agreement.

17.5. Carbogen hereby specifically declares on its own behalf and on behalf of any of its employees that it [***]. Furthermore, Carbogen hereby declares that it [***]. Carbogen declares in this connection on its own behalf and on behalf of any of its employees that it is willing to sign any additional document necessary to [***]. Carbogen shall use its best endeavours to have any third party [***].

17.6. Intellectual Property Rights owned by Ascendis or licensed to Ascendis are necessary for Carbogen to perform its obligations hereunder and to obtain the benefit of its rights under this Agreement. Accordingly, Ascendis hereby grants to the extent necessary to Carbogen a [***] solely [***] and solely [***]. [***] the use of such Intellectual Property Rights [***].

18. INSURANCE AND LIABILITY

18.1. [***] written request prove to have taken out, insurance in order to cover damages on Product while in the custody of [***].

18.2. [***] written request prove to have taken out, a civil liability insurance in order to cover liabilities imposed on [***] under national legislation and/or EU directives/regulations (a) as a consequence of any and all obligations under this Agreement [***] (b) as a consequence of negligent acts and/or omissions by [***], including, without limitation [***] other treatment of Product.

18.3. A Party (the "Indemnifying Party") shall indemnify the other Party, its directors, officers and employees, for any and all damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred in connection with any claim, action or proceeding to the extent proven in a court of competent jurisdiction to have arisen from the negligence or intentional misconduct of the Indemnifying Party or such breach by the Indemnifying Party of any of its obligations under this Agreement.

18.4. The Indemnifying Party shall be entitled, at its option, to control the defense and settlement of any claim for which it is liable hereunder, provided that the Indemnifying Party shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of the claim as the disposition or settlement relates to the party entitled to indemnification. The indemnified party shall reasonably cooperate in the investigation, defense and settlement of any claim for which indemnification is sought or provided hereunder and shall provide prompt notice of any such claim or reasonably anticipated claim to the Indemnifying Party.

18.5. Neither Party shall be liable for any indirect, consequential losses and damages, punitive damages, anticipated or lost profits, business interruption, incidental or special damages, loss of time, or other similar losses in connection with this Agreement whether arising under any legal theory of liability (including under any indemnification obligation) regardless of whether such Party knew or should have known of the possibility of such damages.

18.6. In the event of [***], Carbogen's liability towards Ascendis [***].

18.7. In the event of [***], Carbogen's liability towards Ascendis [***].

18.8. In the event of [***] related to [***], Carbogen's liability [***].

19. REPRESENTATIONS AND WARRANTIES

19.1. Carbogen hereby represents and warrants the following:

a) it has obtained (and will maintain throughout the existence of this Agreement) all necessary approvals, licenses or registrations necessary or desirable for the performance of the Services,

b) it has the necessary experience to perform the Services,

c) the personnel that Carbogen causes to be applied in the performance of the Agreement shall be appropriately qualified and experienced for the tasks that they are to perform,

d) any machinery and equipment that Carbogen provides or causes to be applied in the performance of the Agreement shall be of an appropriate quality and, as required by normal practice shall be qualified and approved by the relevant body or organization,

e) the Services are conducted in compliance with the laws as applicable at its domicile or by the relevant Purchase Order and relevant standards, such as but not limited to cGMP,

f) the Services are conducted in compliance with relevant FDA, EMA and PMDA rules and regulations,

g) Carbogen is not debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. Sec. 335a(a) or any foreign equivalents, and

h) in the event that during the term of this Agreement Carbogen (i) [***], Carbogen agrees to immediately notify Ascendis and shall immediately cease all activities relating to this Agreement.

i) Carbogen has no knowledge, as of the Effective Date, of [***].

19.2. Ascendis represents and warrants to Carbogen that

a) Ascendis is the owner or licensee or otherwise has the right to use and provide to Carbogen all information provided to Carbogen relating to Product, and

b) it has and shall maintain all federal, state and local licenses or registrations necessary for the storage, supply and sale of the Product to third parties (i) each such license or registration is valid and in full force and effect, (ii) there is no pending or to its knowledge threatened, suspension, revocation or cancellation of any such license or registration, and (iii) there is no basis for believing or reasonably expecting any such license or registration will not be renewable upon expiration.

20. ASSIGNABILITY AND SUB-CONTRACTING

20.1. Except as stated otherwise in this Agreement neither Party shall be entitled to assign or sub-contract its rights and/or obligations hereunder in whole or in part to any third party, including any affiliated companies unless having obtained the other Party's prior written approval, provided, however, that Ascendis is free to assign its rights and obligations, including (without limitation) to a third party acquiring, by purchase or license, rights to further develop or commercialize Ascendis' [***] product, [***].

21. FORCE MAJEURE

21.1. Neither Party shall be liable for non-performance of any provisions of this Agreement due to force majeure as defined below.

21.2. Force majeure shall include strikes, lockouts, other industrial disturbances, rebellions, epidemics, landslides, earthquakes, fires, storms, floods, sinking, droughts, civil disturbances, explosions, act or decisions of duly constituted national government authorities or of courts of law, impossibility to obtain equipment, supplies, fuel or other required materials, unexpected toxicity findings of Product, beyond the control of the Party pleading force majeure preventing this Party from performing its rights and obligations and not to be overcome by due diligence of such Party and which could not reasonably have been foreseen at the time accepting the relevant order, provided neither Party shall have any obligation to settle a labour dispute in order to exercise due diligence.

21.3. The Parties agree that if either of them finds themselves wholly or partly unable to fulfil their respective obligations under this Agreement by reasons of force majeure, the Party pleading force majeure will as soon as possible notify the other Party of its inability to perform, giving a detailed explanation of the occurrence which excuses performance. Except from the payments of funds that are due and payable prior to any force majeure neither Party shall be required to make up for any performance that is prevented by force majeure.

21.4. However, if the force majeure persists for a period of more than [***], and the Party pleading force majeure cannot present a remedial action plan acceptable to both Parties within the said [***], the non-failing Party shall be entitled to terminate this agreement with immediate written notice.

22. ARBITRATION AND LAW

22.1. In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the breach, termination or invalidity thereof, the Parties shall try to settle the problem amicably between themselves. Should they fail to agree, the matter in dispute shall be settled by arbitration in accordance with the Arbitration Rules of [***]. The award rendered shall be final and binding and enforceable by any court having jurisdiction. The arbitration court shall consist of [***] and shall have its seat in [***]. The language of the proceedings shall be English. The Institute shall appoint [***] on request by a Party hereto.

22.2. This Agreement shall be governed by and construed in accordance with [***] Law without regard to its conflict of law rules.

23. MISCELLANEOUS

23.1. This Agreement and all Appendixes constitutes the entire agreement between the Parties concerning the subject matter hereof and supersedes all written or oral prior agreements or understandings with respect thereto, except any secrecy agreements made by the Parties, which shall survive the obligations undertaken hereunder. No variation or modification of the terms of this Agreement nor any change of any of the terms or provisions hereof shall be valid unless stated in an amendment to this Agreement. This notwithstanding, any Appendix associated with this Agreement shall be valid if signed by an Authorised Representative of each party.

23.2. The headings contained in this Agreement are for convenience and reference purposes only and shall not affect the meaning of the interpretation of this Agreement.

23.3. The provisions of this Agreement are separate and divisible, and the invalidity or unenforceability of any part shall not affect the validity or enforceability of any remaining part or parts, all of which shall remain in full force and effect. However, the Parties agree to substitute any invalid or unenforceable provision by a valid and enforceable arrangement, which achieves to the greatest extent possible the financial balance and mutual understanding already established between the Parties.

23.4. The Appendices to this Agreement shall form an integral part of the Agreement and shall be regarded as incorporated into the Agreement in every respect. In case of inconsistency between the terms and conditions of the said Appendices and this Agreement, the latter shall prevail to the extent of such inconsistency, except that in quality related matters, the Quality Agreement shall prevail.

23.5. All communication between the Parties and all notices made hereunder shall be made in the English language unless public authorities may require any written communication to be made in any other language and if so the Party submitting to the other Party and/or suggesting such written communication shall upon request from the other Party provide a proper translation hereof into English (certified by an authorised translator should the receiving party so require).

23.6. In the implementation of and performance under this Agreement, each Party shall comply with any and all relevant and applicable laws. Such compliance shall be the sole responsibility of such Party requiring no supervision, direction, responsibility or liability on behalf of the other Party.

23.7. Agreement shall be valid or binding upon the Parties hereto unless made in writing and duly executed on behalf of each Party hereto.

(Signatures on next page)

In witness thereof, the Parties hereto have caused this Agreement to be executed in duplicate by their duly authorised representatives.

Hellerup, October 10th 2018

Ascendis Pharma A/S

/s/ Michael Wolff Jensen
Michael Wolff Jensen
Senior Vice President

Bubendorf, ... 26 October..... 2018

CARBOGEN AMCIS AG

/s/ Dr. Thomas Hartmann
Dr. Thomas Hartmann

Senior Head of Key Account Services
CARBOGEN AMCIS AG

/s/ S. Fritschi
S. Fritschi
Vice President Operations

APPENDIX 1

Approved Manufacturing Sites

[***]

APPENDIX 2

Product

Article number: [***]

Article name: [***]

Wherever amounts of [***] are mentioned they refer to [***].

- **Materials not part of the Product but manufactured and delivered under this Agreement, [***]**

Purchase Price

- Service Fee for manufacture of [***]

- Service Fee for manufacture of [***]

The above Service Fees include [***].

Estimated cost for [***]: [***]

Other Service Fees:
[***]

Other Services, as specified in APPENDIX 7, to be priced separately.

[***]

After a transition period of at least [***] the parties shall [***].
If one of the first [***] batches is rejected due to [***], the parties shall mutually agree on how to share the cost of this defective batch.

APPENDIX 4

Quality Agreement

At any time the current version of the “Commercial Quality Agreement Supplement to Master Services Agreement” to the Master Services Agreement will apply.

APPENDIX 5

Specifications

[***]

APPENDIX 6

Batch Sizes

Batch sizes are in accordance to [***].

Other Services

- Carbogen shall perform stability studies according to a stability program to be agreed and invoiced as separate work orders.
- Carbogen shall be responsible for the preparation and qualification of relevant reference standards, such work to be agreed and invoiced as separate work orders.
- Manufacture of [***] to be agreed and invoiced as separate work orders
- [***] to be agreed and invoiced as separate work orders
- [***] to be agreed and invoiced as separate work orders.

Please note that this list is non conclusive.

APPENDIX 8

Materials

Key raw materials manufactured at CARBOGEN AMCIS within separate work orders:
[***]

Key raw materials requiring product specific supplier qualification for Product:
[***]

Key raw materials without requirement of a product specific supplier qualification for Product (quality relevant raw materials)
(Ascendis approval according to section 7.1 not required):
[***]

Other Productn specific raw materials and Product containers
(Ascendis approval according to section 7.1 not required):
[***]

APPENDIX 9

List of applicable Intellectual Property Rights

[***]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

(1) FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED

AND

(2) ASCENDIS PHARMA A/S

COMMERCIAL SUPPLY AGREEMENT

CONTENTS

THIS AGREEMENT IS BETWEEN

(1) **FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED** incorporated and registered in England and Wales with company number 05803359 whose registered office is at Belasis Avenue, Billingham, TS23 1LH, England ("**Fujifilm**"); and

(2) **ASCENDIS PHARMA A/S** incorporated and registered in Denmark with registration number 29918791 whose registered office is at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark (the "**Customer**"),

each individually a "**Party**" and collectively "the **Parties**".

BACKGROUND

(A) Fujifilm is a biopharmaceutical contract development and manufacturing organization. The Customer wishes to appoint Fujifilm to supply batches of certain of the Customer's products for commercial use in the Territory.

(B) Fujifilm and the Customer have agreed to work together on the terms and conditions contained in this Agreement.

AGREED TERMS

1. DEFINITIONS AND INTERPRETATION

1.1 In this Agreement the following words have the following meanings unless inconsistent with the context:

"Affiliate"	in respect of either party, any company from time to time directly or indirectly Controlling, Controlled by or under common Control with that party;
"Application"	the Customer's biologics license or new drug application and marketing authorization application;
"Applicable Laws"	those UK, EU laws issued by the European Commission and US laws, regulations and binding guidance, in each case to the extent applicable to the Program, together with the laws, regulations and binding guidance of other countries agreed to be added pursuant to clause 5.4;
"Ascendis Material"	a consumable item used or intended for use in a Program, being one supplied [***] by Ascendis, including [***];
"Background IP"	all Intellectual Property Rights controlled, owned or jointly owned by either Party (or a third party on its behalf) prior to the Effective Date or developed independently from the Program;
"Batch"	a quantity of an Intermediate Product, the Product or [***] Reagent that is produced from a run of the applicable Process;

“Business Day”	a day other than a Saturday, Sunday or public holiday in England and/or the country in which the Customer’s head office is located;
“Campaign”	a series of at least 2 Batches of the same Product, or Intermediate Batches used in the manufacture of the Product, purchased in sequence using the same manufacturing equipment ([***]);
“Campaign Price”	has the meaning given to it in paragraph 1.8 of Schedule 1;
“cGMP”	Current Good Manufacturing Practice as defined in (i) the Federal Register volume 66 No 186 and those sections applicable within the FDA Regulations 21 CFR Part 210, 211, 600, 601 and 610 and (ii) the rules governing medicinal products in the European Union. Volume 4 – Guidelines for good manufacturing practices for medicinal products for human and veterinary use. Part II – Basic Requirements for Active Substances used as Starting Materials and ICHQ7 and (iii) any similar UK specific regulations potentially coming into force after 19 March 2019;
“Change”	has the meaning given to it in clause 0;
“Charges”	has the meaning set out in clause 8.1;
“Commercially Reasonable Efforts”	with respect to the activities pursuant to a Program, the reasonable efforts and resources used by a reputable biopharmaceutical contract manufacturing organization for drug substances of similar nature, complexity and developmental stage in the same or similar circumstances;
“Confidential Information”	the fact and terms of this Agreement and all information (in whatever form) in respect of the business of each of the Parties and each of its Affiliates including any ideas; business methods; finance; prices, business, financial, marketing or development plans; products or services, know-how or other matters connected with products or services manufactured and/or marketed; customer lists or details; computer systems and software; which is (in each case) provided or obtained by one Party to or for the other;
“Conforming Batch”	a Batch of Product which has been produced in accordance with cGMP and which meets the Product Specification and a Batch of Intermediate Product [***] which has been produced in accordance with cGMP and which meets the [***] Reagent Specification or the Intermediate Product Specification, as applicable;

"Consumable"	a consumable item used or intended for use in a Program, being one supplied by Fujifilm, including [***];
"Control"	(a) any power (whether directly or indirectly and whether by the ownership of share capital, the possession of voting power, contract or otherwise) to appoint and/or remove all or such of the members of the board or other governing body of a body corporate as are able to cast the majority of the votes capable of being cast by members of that board or body on all, or substantially all, matters, or otherwise to control or have the power to control the policies and affairs of that body corporate; or (b) the holding and/or possession of the beneficial interest in and/or the ability to exercise the voting rights applicable to shares or other securities in any person (whether directly or indirectly) which confer in aggregate on the holders thereto 50% or more of the total voting rights exercisable at general meetings of that body corporate on all, or substantially all, matters, and "**Controlled**" and "**Controlling**" shall be construed accordingly;
"Customer Deliverable"	the deliverables to be supplied by the Customer listed in Schedule 4;
"Customer Foreground IP"	all Foreground IP that constitutes an improvement or modification which [***] to the Customer's Background IP [***];
"Dedicated Equipment"	Fujifilm equipment in the Facility that is dedicated to the Customer;
"Deviation"	a cGMP deviation as detailed in the Quality Agreement;
"Disposition"	the part of the Program during which (i) the Product or [***] or Intermediate Product is tested for compliance versus the Product Specification; (ii) all production instruction and analytical records relating to cGMP manufacture of each Batch prepared by Fujifilm are reviewed; and (iii) a Fujifilm recommendation for Product release or reject is made; in each case as applicable;
"Drug Product"	the final dosage form of product which contains Product in association with other active or inactive ingredients [***];

“Effective Date”	the date of signature by all Parties to this Agreement;
“Facility”	any of Fujifilm’s manufacturing facilities in which a Program will be performed;
“Force Majeure Event”	any event or circumstances outside the reasonable control of a Party affecting its ability to perform any of its obligations under this Agreement including act of God, fire, flood, severe weather, epidemic or pandemic, war, revolution, acts of terrorism, riot or civil commotion, acts of government, trade embargo, labour disputes (excluding labour disputes involving the Party in question), interruption of utility service, restraints or delays affecting shipping or carriers, (where proper precautions have been taken by the party suffering the event or circumstance) inability or delay in obtaining supplies of adequate or suitable materials, (where proper precautions have been taken by the party suffering the event or circumstance) breakdown or failure in equipment or machinery, (where proper precautions have been taken by the party suffering the event or circumstance) cyber-attack, currency restrictions, and illness affecting a material number of the Program team, but shall not include the failure of Drug Product in clinical trials or failure of Drug Product to gain, or loss of, regulatory approval;
“Forecast Date”	has the meaning given to it in paragraph 2.1 of Schedule 2;
“Foreground IP”	all Intellectual Property Rights that arise or are obtained or developed by or on behalf of either Party in the course of the performance of a Program;
“Fujifilm Foreground IP”	all Foreground IP [***];
“Half Year”	has the meaning given to it in paragraph 2.1 of Schedule 2;
“Health Authorities”	shall mean any national or international health authority including but not limited to those of the European Union, and the United States;
“Indemnify”	on demand to indemnify and keep indemnified, and hold harmless, the Party to be indemnified on an after tax basis;
“Initial Term”	the period from the Effective Date until 31 December in the year in which the fifth anniversary of the Launch Date falls;

"Intellectual Property Right"	any current and future intellectual property rights and interests including patents, utility models, designs, design rights, copyright (including rights in software), decryption rights, database rights, trade marks, rights pursuant to passing off, service marks, business and trade names, domain names, know-how, results, data, databases, formulations, compounds, rights in biological or chemical materials, rights under data exclusivity laws, rights under unfair competition laws, topography rights, inventions, rights in confidential information (including technical and commercial trade secrets); supplementary protection certificates and image rights, and rights of a similar or corresponding character in any part of the world, in each case whether registered or not and including any application for registration and renewals or extensions of such rights in any country in the world and whether subsisting now or in the future;
"Intermediate Batch"	a Batch of an Intermediate Product that is produced from a run of the [***] intermediate element of the Process;
"Intermediate Products	[***] the recombinant human growth hormone (hGH) produced as part of [***];
"[***]"	has the meaning given to such term in clause 5.8.4
"Joint Steering Committee"	the committee formed and operated by the Parties, which shall act in resolving disagreements and disputes between the Parties, discuss and evaluate the mutual cooperation and in good faith negotiate and decide upon issues;
"Key Assumptions"	the key assumptions set out in part 2 of Schedule 2;
"KPI"	a key performance indicator agreed by the Joint Steering Committee pursuant to clause 3.2.7;
"Launch Date"	the date the Drug Product is first made available by the Customer in any country for sale as an approved drug for the treatment of patients;
"Liabilities"	any (i) liabilities whether in contract, tort (including negligence) or otherwise; (ii) losses, costs (including internal costs/overheads), damages, fines or expenses including reasonable legal fees; and (iii) claim, demand, proceeding, action or cause of action; in each case howsoever arising. "**Liability**" shall be construed accordingly;
"Materials"	has the meaning given to it in clause 7.1;
"Maximum Annual Quantity"	as set out in Schedule 2;
"Minimum Annual Quantity"	as set out in Schedule 2;
"Non-Conforming Batch"	a Batch which has not been produced in accordance with cGMP and/or does not meet, as appropriate, the Product Specification or the [***] Specification or the Intermediate Product Specification;

“Order”	has the meaning given to it in Schedule 2;
“Pass Through Costs”	has the meaning given to it in Schedule 1;
”PPQ”	Process Performance Qualification
“Process”	the particular process used, or to be used, for manufacture of the Product or the [***] Reagent, as applicable;
“Process Specification”	the Process specification which is a QA Document;
“Product”	TransCon [***] human growth hormone (hGH);
“Product Specification”	the Product specification which is documented in a QA Document;
“Production Year”	a period of twelve (12) consecutive calendar months ending on 31st December, the first Production Year commencing [***];
“Program”	the production, testing and Disposition (if applicable) of Batches including pre and post manufacturing activities (such as campaign set up and Facility change-over) to be performed under this Agreement;
“Program Manager”	the Program manager appointed by each of Fujifilm and the Customer under clause 3.1;
“Quality Agreement”	the single document agreed by the Parties which sets out the mutually agreed quality standards applicable for the cGMP manufacture of the Products, Intermediate Products, and [***] Reagent, including documentation requirements, notification, sampling, testing, rejections, complaints handling, deviation handling, CAPAs, change control, reporting and recall mechanisms;
“QA Documents”	the Quality Agreement and the documents produced and approved in accordance with the Quality Agreement;
“Recall”	has the meaning given to it in clause 9.6;
“Regulatory Authority”	the U.S. Food and Drug Administration, the European Medicines Agency, the Medicines & Healthcare products Regulatory Agency and any successor to any such entities;
“Subcontracted Work”	work subcontracted by Fujifilm under clause 21.3;
“Shelf Life”	the shelf life of Materials, detailed in the Storage Agreement;

"Storage Agreement"	the terms and conditions for storage of [***] Reagent, the Intermediate Products (to the extent [***]) and Product, set out in Schedule 5;
"Tax"	value added tax, sales tax or any other similar type of turnover tax;
"Territory"	worldwide
"[***] Reagent"	the [***], known as [***];
"[***] Specification"	the Process specification for the [***] Reagent, which is documented in a QA Document; and
"Year"	each period of 12 (twelve) consecutive months commencing on the Effective Date or an anniversary of the Effective Date, the final last Year commencing on the last anniversary of the Effective Date and ending on the date of termination or expiry.

1.2 In this Agreement (except where the context otherwise requires) any words following the terms "**including**", "**include**", "**for example**" or any similar expression are by way of illustration and emphasis only and shall not limit the generality or extent of any other words or expressions.

1.3 Insofar as this Agreement obliges either Party to this Agreement to negotiate, take action or to do something, that Party shall conduct such negotiations, take such action or do such thing in good faith and, in the case of Fujifilm, using Commercially Reasonable Efforts to achieve the result contemplated in this Agreement. There shall be a general obligation on the Parties to act in good faith in relation to the matters contemplated in this Agreement.

1.4 In the case of conflict or ambiguity between terms of the main body of this Agreement or any Schedule to this Agreement the main body of the Agreement shall prevail. In the case of conflict or ambiguity between the terms of this Agreement and the terms of the QA Documents, the terms of the QA Documents shall prevail solely in relation to cGMP quality matters subject to clause 9.9.

1.5 Where a defined term is used in clause 9 (Liability) it shall retain its meaning even when the entire word that is a defined term is in capitals.

2. APPOINTMENT AND TERM

2.1 This Agreement establishes the general terms and conditions applicable to Fujifilm's post-PPQ supply of the Products to the Customer. All Orders made by the Customer to Fujifilm for Product during the term of this Agreement are subject exclusively to the terms and conditions of this Agreement and any standard terms of the Customer referenced in an Order for Products shall not apply.

2.2 This Agreement shall come into force on the Effective Date and shall, unless terminated earlier by a Party in accordance with clause 15, continue for the Initial Term and thereafter unless and until terminated in accordance with clauses 2.3, 2.4 or 2.5.

2.3 The Customer may terminate this Agreement by giving no less than 2 (two) years' prior written notice to Fujifilm, such notice to be served at the earliest at the end of the last day of the Initial Term. For example, the earliest termination can occur

is the seventh anniversary of the Launch Date. The Customer shall, in its sole discretion, either accept delivery of binding Orders and other minimum purchase commitments or shall pay to Fujifilm the price for all undelivered binding Orders and other minimum purchase commitments detailed in this Agreement, including those Orders and commitments that extend beyond the date of termination.

2.4 The Customer may terminate this Agreement (and related Orders) in respect of the Intermediate Products (but not in respect of the Product) by giving no less than 2 (two) years' prior written notice, such notice to be served at the earliest at the end of the last day of first year following the Launch Date. For example, the earliest termination can take effect is the third anniversary of the Launch Date. The Customer shall in its sole discretion either accept delivery of binding Orders and other minimum purchase commitments or shall pay to Fujifilm the price for all undelivered binding Orders and other minimum purchase commitments detailed in this Agreement, including those Orders and commitments that extend beyond the date of termination.

2.5 Fujifilm may terminate this Agreement (and all Orders made under it) by giving no less than 5 (five) years' prior written notice to the Customer, such notice to be served at the earliest at the end of the last day of the Initial Term. For example, the earliest termination can take effect is the tenth anniversary of the Launch Date.

2.6 This Agreement does not supersede the agreement dated 24th April 2015 between the Parties for the supply of product development services in relation to the Product (the "**Development Agreement**"). The Development Agreement shall continue to apply in respect of pre-commercial manufacture of the Product, including the batches manufactured as part of the PPQ.

3. PROGRAM MANAGEMENT, FORECASTING AND ORDERS

3.1 Within [***] of the Effective Date each Party will appoint a Program Manager to oversee and manage the execution of its obligations under this Agreement. The Program Managers shall each be the primary contact for the other Party in relation to this Agreement and will be responsible for managing any Changes. The Program Managers' responsibilities shall include being the—or appointing a—primary logistics contact for communications regarding forecasts, orders, delivery and shipping. If either Party changes its appointed Program Manager it will promptly notify the other in writing.

3.2 **Joint Steering Committee**

3.2.1 Composition. A Joint Steering Committee shall be established consisting of representatives from each Party with the requisite experience and sufficient seniority to enable them to make decisions on behalf of the Parties. The Parties shall agree the number of representatives, provided an equal number of representatives of Fujifilm and the Customer must be appointed. Each Party will designate its representative(s) to the Joint Steering Committee within [***] of the Effective Date.

3.2.2 Purposes. The Joint Steering Committee shall have the responsibility to (i) oversee planning for the Program; (ii) oversee the Parties' performance under this Agreement; (iii) review matters such as the appropriate [***] of the Intermediate Product and [***] Reagent; (iv) consider qualified back-up manufacturing and such other matters as they deem appropriate to protect against the risk of interruption of supply, whether due to the occurrence of a Force Majeure Event or otherwise; (v) consider opportunities for mutual cooperation. [***]

3.2.3 Substitutions. Each Party may substitute one or more of its representatives, in its sole discretion, effective upon written notice to the other Party of such change, provided that any such substitute shall have the requisite experience and seniority, together with such Party's other representatives on the Joint Steering Committee, to make decisions on behalf of such Party.

3.2.4 Meetings. [***] shall be responsible for organizing and chairing the Joint Steering Committee meetings. The Joint Steering Committee shall meet not less than [***] on such dates and at such times as agreed to by the Parties. It is expected that the meetings shall be held by telephone or video conference, provided that at least [***] the Joint Steering Committee meets face-to-face, at a mutually agreed location. Either Party may call for a meeting (by telephone or video conference) of the Joint Steering Committee at any other time upon the service of [***] written notice, such notice to indicate the primary purpose of the additional meeting. Each Party may permit visitors, including its employees or agents, who are not members of the Joint Steering Committee to meetings of the Joint Steering Committee, as the Parties mutually agree in writing prior to such meetings; provided, however, that the Party that permits such visitors to attend any meeting of the Joint Steering Committee shall ensure that they agree in writing or otherwise to be bound by confidentiality obligations at least as protective as the provisions of clause 13 prior to attending such meeting. Each Party shall bear the cost of its attendance, including travel and hotel costs and other expenses incurred by its representatives.

3.2.5 Operational update for first Campaign. At least [***] prior to the manufacture of the first Batch of the first Campaign, the Joint Steering Committee will meet to agree on operational details of the Process, including the taking and analysis of in-process samples.

3.2.6 Post-approval Changes. Any significant post-approval changes requested by either Party will be discussed and agreed by the Joint Steering Committee, except where they are required by a change in Applicable Law in which case clauses 14.2 and 14.3 shall apply. Any other significant post-approval change shall be adopted as follows:

(a) either Party may notify the other of a post-approval change that it, acting reasonably, considers to be significant. If the other Party disagrees that the proposed change is significant, the Joint Steering Committee shall review and determine whether it is prepared to review the change or require it to be dealt with by the regular change process in clause 0;

(b) if the Joint Steering Committee agrees to review a significant change, the Party requesting the change shall submit a change proposal detailing the change, the costs, the benefits and other relevant factors to each of the members of the Joint Steering Committee at least [***] prior to the meeting at which the change is to be discussed;

(c) the Joint Steering Committee shall review and discuss the proposed change and agree the key commercial terms of the change, including price, investment, timings and dependencies on the Parties. This agreement shall be recorded in the minutes of the meeting;

(d) it may require more than one meeting of the Joint Steering Committee to conclude discussions on the change and the Parties shall agree in each meeting what the respective Party's commitments are prior to the next meeting;

(e) once the principles of a significant change have been agreed by the Joint Steering Committee the Parties shall conclude the change using the processes determined in clause 0 (save that the Parties agree to skip any stages that have in effect been covered by the Joint Steering Committee's review of the proposed changes); and

(f) any change that is not deemed a significant change by the Parties shall be managed in accordance with clause 0.

3.2.7 Performance Review.

(a) The Joint Steering Committee shall agree [***] to monitor and measure Fujifilm's and Customer's performance under this Agreement.

(b) [***], each Party shall be responsible for recording its performance [***].

(c) The Joint Steering Committee shall at each Joint Steering Committee meeting review each Party's performance [***]. If a Party fails to meet [***], then the Joint Steering Committee shall review the reasons why the failure(s) arose and shall agree what measures, if any, it should recommend that the Party should adopt to [***].

3.2.8 Minutes. Within [***] following each Joint Steering Committee meeting, a representative of the chairing Party shall prepare and provide to each Party a copy of the minutes of such meeting which shall set forth, in reasonably specific detail, any approval, determination or other action agreed to by the Joint Steering Committee, provided that such minutes are reasonably acceptable to both Parties.

3.2.9 Dispute Resolution. Any disputes or disagreements arising in the Joint Steering Committee that cannot be resolved by its members within [***] of having been brought to the Joint Steering Committee, shall be referred to the dispute escalation mechanism in clause 17.

3.2.10 Fujifilm Independence. The Parties acknowledge and agree that Fujifilm shall have the right to make day-to-day operation decisions regarding the implementation and conduct of the Program in accordance with this Agreement. For the avoidance of doubt, (i) nothing contained in this clause 3.2 nor any decisions made by the Joint Steering Committee, shall relieve either Party of its obligations under this Agreement, and (ii) the Joint Steering Committee shall not have the authority to amend this Agreement or waive any breach hereof.

3.3 Product, [***] Reagent and Intermediate Products [***] will be forecast, and Product and [***] Reagent and Intermediate Product [***] will be ordered, in accordance with Schedule 2.

4. CAPACITY AND EXPANSION TERMS

4.1 Initial Reservation

Fujifilm reserves sufficient capacity at the Facility to manufacture for the Customer at least [***] of the Product [***]. Fujifilm acknowledges that this includes [***]. [***] [***].

4.2 [***]

4.2.1 [***].

4.2.2 [***].

4.2.3 [***]

5. MANUFACTURE OF PRODUCTS

5.1 Fujifilm shall produce each Batch in accordance with:

5.1.1 the terms of this Agreement;

5.1.2 Applicable Laws;

5.1.3 cGMP and the applicable Quality Agreement;

5.1.4 using Commercially Reasonable Efforts;

5.1.5 in accordance with the applicable Process Specification; and

5.1.6 such that the Product, Intermediate Product ([***]) and [***] Reagent meets the applicable specifications.

5.2 The Customer shall:

5.2.1 promptly provide the Customer Deliverables at the times set out in Schedule 2;

5.2.2 meet all its obligations and responsibilities under this Agreement and the applicable Quality Agreement (either that for the Product and related Intermediate Products, or for the [***] Reagent);

5.2.3 comply with Applicable Laws; and

5.2.4 promptly provide all assistance, information, and advice and do all acts which Fujifilm may reasonably request to enable Fujifilm to comply with its obligations and responsibilities under this Agreement and the applicable Quality Agreement (either that for the Product and related Intermediate Products, or for the [***] Reagent).

5.3 Fujifilm's delivery of Programs and each Batch depends upon Customer's compliance with clause 5.2. Fujifilm will not be in breach of any obligation under this Agreement (including to deliver an Order and/or the Minimum Annual Quantity) if failure to meet that obligation is caused by Customer's breach of or delay in performance of any obligations under clause 5.2 and Customer will still be obligated to pay for the affected Order(s) and/or the Minimum Annual Quantit(ies) (as applicable).

5.4 [***]

[***]

5.5 Quality Agreement

5.5.1 The Parties have previously executed the Quality Agreement (Current version 3.00 dated 04 May 2018) in respect of the Product, the related Intermediate Products and the [***] Reagent.

5.5.2 The Customer acknowledges that Fujifilm shall not commence any activity under this Agreement until the applicable Quality Agreement is executed by both Parties.

5.6 Regulatory Assistance

5.6.1 The Customer shall provide Fujifilm with a copy of relevant parts of the Customer's Chemistry, Manufacturing and Controls section of any submission to a Regulatory Authority supporting an Application made by the Customer's for the applicable Drug Product (whether the biologics license application or marketing authorisation application), the [***] Reagent or the applicable Process, relevant parts being any part relating to Fujifilm's manufacture of the Product ("**CMC Section**") and any change thereto with enough time for Fujifilm to review and comment on the same before submission to such Regulatory Authority, provided, however, that Fujifilm shall use Commercially Reasonable Efforts to perform its review and that such review by Fujifilm shall not be unreasonably withheld. The Customer shall not submit a CMC Section without Fujifilm's written approval in relation to any information regarding, or impacting, Fujifilm including any information regarding the Process, equipment, controls and analytics or any information provided to the Customer by Fujifilm related to or in accordance with the applicable Quality Agreement. If the documents or support required from Fujifilm pursuant to this clause 5.6.1 relate [***], then Fujifilm may [***].

5.6.2 After the completion of the PPQ the Parties shall agree on the level of continuous process verification to be applied by Fujifilm (which may be itself subject to an agreement change). If the Customer requires any support in relation to regulatory documentation regarding continuous process verification over and above the level agreed, then Fujifilm may agree to provide that assistance [***].

5.6.3 Fujifilm will provide one electronic (PDF) copy of any documents which may be reasonably required by the Customer in support of its Application. If the Customer requires copies of the laboratory notebooks, provision of these will be subject to discussion and agreement by the Parties and agreement of [***].

5.6.4 The Customer shall have the right and responsibility for determining regulatory strategy, decisions and actions relating to the Product and/or Drug Product (including any BLA) and/or [***] Reagent subject to clause 5.6.5 and provided that Fujifilm shall have the right and responsibility for determining regulatory strategy, decisions and actions to the extent relating to:

(a) the Facility (including in particular utilities and equipment);

(b) Fujifilm's quality systems, policies and internal procedures;

(c) any requirement imposed on Fujifilm by a Regulatory Authority; or

(d) any other commitments made by Fujifilm prior to the Effective Date,

(each a "**Fujifilm Regulatory Responsibility**").

5.6.5 Fujifilm is obligated to support regulatory requirements and requests [***] Health Authority Requirements are in this context defined as direct legal requirements imposed on Customer in the respective region where non-compliance results in loss of license to operate or financial penalties due to non-compliance. Health Authority Requests are defined as enquiries from Health Authorities in the respective region with relation to regulatory submissions (including but not limited to marketing authorization applications, clinical trial applications, line extensions, variations and safety requests).

5.6.6 Fujifilm shall use its Commercially Reasonable Efforts to deliver any information/data required to support both Health Authority Requirements and Health Authority requests. Data should be delivered to Customer according to respective Health Authority controlled terms as applicable and where possible in structured format (in a suitable file format).

5.6.7 Fujifilm must make available any information/documentation/data required to support regulatory requirements/requests as soon as reasonably possible and no later than [***] following the first written enquiry from Customer.

5.6.8 The Customer acknowledges that Fujifilm's Quality Assurance team reserves the right to Disposition Product and [***] Reagent to the Customer in accordance with the applicable Quality Agreement.

5.6.9 The Customer shall not make any change to its regulatory filings, including any Application, which may have an impact on any Fujifilm Regulatory Responsibility or Fujifilm's performance of its obligations under this Agreement without prior written agreement with Fujifilm in accordance with clause 0.

5.7 Storage

5.7.1 Where Product, Intermediate Product and [***] Reagent is specified in clause 5.8 as being stored by Fujifilm in accordance with the terms of the Storage Agreement:

(a) the storage will be subject to a separate Product-specific schedule that will be deemed to form part of the Storage Agreement in Schedule 5;

(b) the Parties may vary the operational content of the Storage Agreement in accordance with clause 0.

(c) the Customer shall [***] in respect of all items stored by Fujifilm.

5.8 Agreed inventory management principles

Fujifilm agrees that it shall adopt the following inventory management principles in supporting the Program.

5.8.1 Fujifilm will purchase long-lead time Consumables on receipt of the Order and other Consumables in good time for scheduled production. Consumables are charged to the Customer in accordance with Schedule 1.

5.8.2 Fujifilm will store the [***] in accordance with the Storage Agreement. Fujifilm will [***]. The Customer will [***] in line with [***]. Fujifilm is not responsible for [***], but must [***]. If Fujifilm [***] (i) the Customer agrees that [***] (ii) to the extent that [***], Fujifilm agrees that it will [***].

5.8.3 Fujifilm will store Intermediate Product in the ordinary course of a Campaign [***].

5.8.4 At the Customer's request (by placement of Orders) [***] Fujifilm will manufacture [***] of each of [***] and intermediate recombinant hGH ([***]) and store [***] in accordance with the Storage Agreement. Orders for [***] must be issued at the same time as Orders for Product and [***]. Fujifilm shall replace [***] that is, through Fujifilm's wilful misconduct, irrevocably harmed.

5.8.5 If the Customer requests, Fujifilm shall store up to [***] of Product in accordance with the Storage Agreement.

5.8.6 Fujifilm shall manufacture [***] Reagent at [***] scale and shall store no less than [***] at any time, in accordance with the Storage Agreement. On each occasion Fujifilm believes the forecast volumes require it, Fujifilm shall notify the Customer that Fujifilm must produce [***] of [***] Reagent. The Customer shall without undue delay issue an order for the volume identified by Fujifilm.

5.9 Freezer capacity

5.9.1 If the frequency of Campaigns increases from that anticipated at the Effective Date, or the number of Batches within Campaigns is increased, such that the volume of Batches of Product ([***]) and any Batches of Intermediate Product produced in accordance with clause 5.8.4 increases such that Fujifilm requires additional freezer space to accommodate the volumes, [***].

6. CONFORMING BATCHES AND NON-CONFORMING BATCHES

6.1 Each Batch will be determined to be a Conforming Batch or a Non-Conforming Batch.

6.2 If during manufacturing Fujifilm discovers any significant Deviation it will inform the Customer in accordance with the reporting requirements set out in the Quality Agreement. The Customer agrees that only Deviations which are determined to affect, as applicable, Product quality, Intermediate Product quality, or [***] Reagent quality will cause a Batch to be classified as a Non-Conforming Batch.

6.3 In respect of Conforming Batches, Fujifilm will complete Disposition, issue a certificate of analysis and a cGMP compliant statement. The provisions of clauses 6.4 to 6.6 shall apply to Non-Conforming Batches only.

6.4 If a Batch is a Non-Conforming Batch (including where the non-conformance is demonstrated by the Customer after delivery) and the cause of that Batch being a Non-Conforming Batch is not a failure by Fujifilm to comply with clause 5.1 then [***]. Any further work in relation to the Non-Conforming Batch (such as analysis of the Batch) or manufacture of a replacement Batch shall [***].

6.5 If a Batch is a Non-Conforming Batch (including where the non-conformance is identified by the Customer after delivery) and the cause of the Batch being a Non-Conforming Batch is a failure by Fujifilm to comply with clause 5.1 then Fujifilm shall [***]. In these circumstances the Customer shall [***]. If the non-conformity is discovered after shipment to the Customer, Fujifilm shall [***]. In addition, in the circumstances described in this clause 6.5 Fujifilm shall [***]:

6.5.1 [***]; or

6.5.2 if the cause of the Non-Conforming Batch is caused by [***].

6.6 If the Customer requests delivery of a Non-Conforming Batch it must make such request to Fujifilm in writing within [***] of being informed that the Batch is a Non-Conforming Batch. Fujifilm agrees to deliver a Non-Conforming Batch to the Customer on the express condition that [***].

6.7 Any dispute regarding conformity shall be resolved in accordance with the dispute process set out in the Quality Agreement, which process shall be final.

7. DELIVERY, TITLE AND RISK

7.1 Delivery by Fujifilm to the Customer of the Products and any other output from the Program which is deliverable to the Customer under this Agreement (including [***]), any Process-Specific Equipment and/or Process-Specific Consumables and return of any Customer Deliverables ("**Materials**") will be made [***] (Incoterms 2010) and clauses 7.2 to 7.7 shall apply to such Materials. Fujifilm shall package the relevant Material ready for shipment in accordance with the Customer's reasonable instructions.

7.2 Delivery of Materials will be deemed to be completed:

7.2.1 in respect of Product, [***];

7.2.2 in respect of [***];

7.2.3 in respect of [***] Reagent, [***];

7.2.4 in respect of any Materials other than those described above, [***],

in each case the point of delivery being as set out in [***] (Incoterms 2010) (the "**Facility**").

7.3 If the Customer fails to collect Materials that have been deemed to be delivered under clause 7.2 Fujifilm shall notify Customer that the Materials are available for collection. If Customer does not collect the Materials within [***] of such notice, Fujifilm may, [***].

7.4 Risk in the Material shall pass to the Customer on the earlier of (i) completion of actual delivery or (ii) the date stated in clause 7.2 that the applicable type of Material is deemed delivered.

7.5 The Customer shall make and pay for all logistics arrangements to collect the Materials in accordance with clause 7.1 and to deliver the supplied items pursuant to clause 7.8.

7.6 If Fujifilm reasonably believes that the scheduled delivery date for a consignment will be delayed beyond the previously agreed dates, it shall promptly advise the Customer in writing of the reason for the delay, the Materials affected and the new estimated delivery date. Fujifilm shall use Commercially Reasonably Efforts to make the Materials available for delivery with as short a delay as reasonably possible.

7.7 Title to the Product shall pass to the Customer [***].

7.8 Delivery of any materials which the Customer is required to supply to Fujifilm pursuant to this Agreement shall be delivered to Fujifilm [***] (Incoterms 2010).

7.9 Risk and title in [***]. [***] Intermediate Products shall not be delivered to the Customer, but rather used in the Campaign to manufacture Product.

7.10 Risk and title in [***] shall pass upon [***].

7.11 Risk and title in [***] Reagent shall transfer to Customer once the Batch has completed Disposition, however it will not be delivered to the Customer but instead will be used in Campaigns to manufacture Product.

7.12 The Customer shall notify Fujifilm within [***] of the date of delivery of Product of any non-conformity of the Product, unless it is a latent defect in which case the Customer shall notify Fujifilm within [***] of the date the latent defect was discovered. If non-conformity (including latent defect) is not notified within [***] of the date of Disposition, the Customer may not (notwithstanding the cause of the non-conformity) make any claim against Fujifilm in respect of the alleged Non-Conforming Batch.

8. PRICE AND PAYMENT

8.1 The Customer shall pay to Fujifilm for each Program:

8.1.1 the Batch Price for each Batch; and

8.1.2 [***],

in each case as set out in Schedule 1 (together the "**Charges**").

8.2 [***]

8.2.1 Within [***] following the end of each Production Year Fujifilm shall notify the Customer of the number of Batches of Product delivered during that Production Year.

8.2.2 If the number of Batches of Product ordered for Delivery within that Production Year is less than the greater of (i) the Minimum Annual Quantity for that Production Year and (ii) the forecast for the Production Year (as determined in accordance with paragraph 2 of Schedule 2) the Customer shall, subject to clause 8.3, [***]. The Customer shall not be required to [***], except to the extent that [***].

8.3 If the Customer reasonably believes that the shortfall in Batches of Product arises directly from Fujifilm's failure to make the required capacity available for the manufacture of such Batches, or from Fujifilm's delay in delivery or by reason of Fujifilm delivering a Non-Conforming Batch, then this shall be discussed, reviewed and resolved by the next meeting of the Joint Steering Committee.

8.4 Fujifilm may invoice the Customer for the Charges in respect of each Program in accordance with the terms set out in Schedule 1.

8.5 Fujifilm may invoice the Customer for Charges [***] at any time following its notice pursuant to clause 8.2. If there is a dispute regarding the number of unrealised Batches of Product, then Fujifilm may [***] and [***] at the following Joint Steering Committee meeting.

8.6 If the Drug Product is or will be marketed in countries [***] the Customer will [***] for all of Fujifilm's country-specific activities for the approval and marketing of the Product in those countries.

8.7 The Customer shall pay each invoice issued to it by Fujifilm within [***] of the date of invoice, in full and in cleared funds [***] by electronic transfer to the financial institution specified in the relevant invoice.

8.8 The Charges are [***], and which shall be payable by the Customer to Fujifilm [***].

8.9 If there is a change in the rate of Tax payable or in the Tax treatment of some or all of the services provided by Fujifilm or the Product, a change of law or practice or interpretation of the existing legislation or revised determination by HMRC (Her Majesty's Revenue and Customs) or the IRS (Internal Revenue Service), or the supply of product by Fujifilm has been incorrectly regarded as Tax exempt, or if the courts rule Tax is chargeable, then the Customer agrees that Fujifilm shall be entitled, where Tax is imposed on a supply by Fujifilm under or in connection with this Agreement (including the retrospective application of Tax upon services which Fujifilm has already performed and which have previously been invoiced on a Tax exempt basis), to invoice the Customer (in a valid Tax invoice) for a sum equal to the amount of the Tax which becomes due on that supply [***]. The Customer shall pay those invoices in accordance with clause 8.7.

8.10 The Customer shall:

8.10.1 [***] taxes, charges, levies, assessments and other fees of any kind imposed by governmental or other authority in respect of the purchase, importation, exportation, sale or other distribution of the Products and any other materials delivered to it by Fujifilm in connection with the Program; and

8.10.2 make all payments under this Agreement without withholding or deduction of, or in respect of, any tax unless required by law. If any such withholding or deduction is required, the Customer shall, when making the payment to which the withholding or deduction relates, [***].

8.11 Without prejudice to any other right or remedy that it may have, if the Customer fails to pay any sum to Fujifilm on the due date for payment:

8.11.1 the Customer shall pay interest on the overdue amount at the rate of [***]. Such interest shall be payable in respect of the period from the due date until actual payment of the overdue amount (whether before or after judgment) in accordance with clause 8.7; and

8.11.2 (except where the Customer has complied with its obligations in clause 8.12 below) Fujifilm may notify the Customer that if it does not pay Fujifilm will suspend work on the Program, and if payment is not made within [***] of such notice, Fujifilm may suspend such work until payment has been made in full.

8.12 If the Customer disputes the payment of any Charges or a part of them, the Customer shall:

8.12.1 notify Fujifilm of the disputed amount within [***] of its receipt of the invoice in which such disputed amount is included giving reasonable details of the dispute; and

8.12.2 pay the amount of Charges not in dispute in accordance with clause 8.7, and the dispute shall be dealt with under the dispute resolution process set out in clause 17.

8.13 If the Customer fails to pay any sum which is not the subject of a bona fide dispute under clause 8.12 when the same is due in accordance with clause 8.7 then Fujifilm may elect, at its discretion, to treat such non-payment as a material breach this Agreement under clause 15.1.

8.14 A Party shall not be entitled to withhold, set off or reduce payment of any amounts payable under this Agreement by any amounts which it claims are owed to it by another Party under this Agreement or any other agreement.

9. LIABILITY

9.1 The Parties agree that:

9.1.1 the potential extent of Liability arising from the supply of the Product is better known to the Customer than to Fujifilm;

9.1.2 the potential extent of such Liability may be disproportionate to Charges agreed for Fujifilm's supply of the Product;

9.1.3 the Customer is better able to, and should, insure against any Liabilities the Customer might suffer,

and that consequently Fujifilm may restrict its Liability as set out in this clause 9 and the Customer should Indemnify Fujifilm in accordance with clauses 9.3, 9.4 and 9.5.3 and the Parties agree that clause 9.2 does not limit or exclude the Customer's Liability to Fujifilm under those indemnities.

9.2 SAVE THAT NOTHING IN THIS AGREEMENT LIMITS OR EXCLUDES THE LIABILITY OF EITHER PARTY TO THE OTHER FOR ANY LIABILITY THAT IS NOT PERMITTED TO BE LIMITED OR EXCLUDED BY LAW (INCLUDING DEATH OR PERSONAL INJURY CAUSED BY A PARTY'S NEGLIGENCE), NOR IN RESPECT OF CLAIMS MADE BY FUJIFILM FOR FULFILMENT OF THE MINIMUM VOLUME COMMITMENTS:

9.2.1 EXCEPT IN RESPECT OF [***], [***]:

(a) UNLESS CLAUSE 9.2.1(B) APPLIES, [***]; OR

(b) FOR [***].

9.2.2 THE PARTIES AGREE TO DISCUSS AN ADJUSTMENT OF [***] IN CASE OF A CHANGE [***].

9.2.3 EXCEPT TO THE EXTENT ARISING FROM GROSS NEGLIGENCE OR WILFUL MISCONDUCT, NEITHER PARTY SHALL BE LIABLE, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), FOR BREACH OF STATUTORY DUTY OR OTHERWISE, ARISING UNDER OR IN CONNECTION WITH THIS AGREEMENT FOR: LOSS OF PROFIT; LOSS OF BUSINESS; DEPLETION OF GOODWILL; LOSS OF ANTICIPATED SAVINGS; LOSS OR CORRUPTION OF DATA OR INFORMATION; OR ANY SPECIAL, INDIRECT, CONSEQUENTIAL OR PURE ECONOMIC LOSS, COSTS, DAMAGES, CHARGES OR EXPENSES, [***].

9.3 Liability for Product and Drug Product: the Customer shall Indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Affiliates arising out of or resulting from [***] the Product or the Drug Product [***].

9.4 Liability for the Process: the Customer shall indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Affiliates arising out of or resulting from [***] the Process (or any part of the Process) except to the extent that [***].

9.5 Liability for Non-Conforming Batches:

9.5.1 THE PROVISIONS OF CLAUSE 6 SHALL APPLY TO NON-CONFORMING BATCHES AND FUJIFILM SHALL [***].

9.5.2 [***] IN RESPECT OF NON-CONFORMING BATCHES OR THE USE BY THE CUSTOMER OF NON-CONFORMING BATCHES.

9.5.3 If the Non-Conforming Batch is delivered to the Customer pursuant to clause 6, [***].

9.5.4 The Customer uses any material produced in a Non-Conforming Batch at its own risk and shall undertake such tests as are necessary in order to satisfy itself that such materials are fit for the purposes for which the Customer proposes to use such materials.

9.6 Recall:

9.6.1 If the Customer is required by a Regulatory Authority or voluntarily chooses to initiate a recall or withdrawal of any Drug Product ("**Recall**"), the Customer shall notify Fujifilm.

9.6.2 Fujifilm shall provide all reasonably requested assistance and information to Customers and cooperate with the Customer to implement the Recall in accordance with the protocols and procedures contained in the Quality Agreement.

9.6.3 The Customer shall [***], unless the sole cause of the Recall is that the Product incorporated into the Drug Product is agreed pursuant to clause 6 to be a Non-Conforming Batch (in which case clause 9.6.4 will apply). If the cause of the Non-Conforming Batch is [***] attributed to the [***], then this will be an item for which the Customer is entirely responsible.

9.6.4 If a Recall of a Batch from sale is necessary and Customer can prove that the Recall was due to a Non-Conforming Batch of Product and the cause of the Batch being a Non-Conforming Batch is a failure by Fujifilm to comply with clause 5.1, Fujifilm shall [***]:

(a) [***]; and

(b) [***],

such [***] being subject to [***].

9.6.5 If the sole cause of the Recall is that the Product incorporated into the Drug Product is agreed pursuant to clause 6 to be a Non-Conforming Batch and that the Non-Conformity was known to the Parties when the Product was Delivered, then clause 9.5 shall apply in respect of the Non-Conforming Batch.

9.7 FUJIFILM GIVES NO, AND DISCLAIMS ANY, WARRANTIES, UNDERTAKINGS OR SIMILAR TERMS WHATSOEVER IN RESPECT OF ANY ADVICE OR ASSISTANCE GIVEN BY FUJIFILM IN CONNECTION WITH [***]; AND FUJIFILM SHALL HAVE NO LIABILITY TO THE CUSTOMER IN CONNECTION WITH ANY SUCH ADVICE OR ASSISTANCE.

9.8 ALL WARRANTIES, CONDITIONS AND OTHER TERMS, EXPRESS (OTHER THAN THOSE SET OUT IN THIS AGREEMENT) OR IMPLIED, STATUTORY, CUSTOMARY OR OTHERWISE WHICH BUT FOR THIS CLAUSE 9 WOULD OR MIGHT SUBSIST IN FAVOR OF THE CUSTOMER, ARE (TO THE FULLEST EXTENT PERMITTED BY LAW) EXCLUDED FROM THIS AGREEMENT INCLUDING, IN PARTICULAR, ANY IMPLIED WARRANTIES RELATING TO MERCHANTABILITY, FITNESS FOR A PARTICULAR USE AND NON-INFRINGEMENT.

9.9 No claim for Liabilities incurred pursuant to the Quality Agreement may be made under the Quality Agreement by either Party. Accordingly, performance of the Quality Agreement shall be deemed to be performance under this Agreement and as such any breach of the Quality Agreement shall be deemed to be a breach of this Agreement and all Liabilities shall be construed and limited in accordance with this clause 9.

9.10 Each Party agrees to take all reasonable steps to mitigate any Liabilities that it may seek to claim from the other under or in connection with this Agreement including pursuant to any Indemnity.

9.11 If a Party is entitled to benefit from an Indemnity (the "**Indemnified Party**") from the other Party (the "**Indemnifying Party**") in accordance with this Agreement (an "**Indemnity Claim**"), the Indemnified Party shall notify the Indemnifying Party in writing of the Indemnity Claim (providing all necessary details) and the Indemnifying Party shall at its own expense conduct all negotiations and any litigation arising in connection with the Indemnity Claim provided always that:

9.11.1 the Indemnifying Party shall consult the Indemnified Party on all substantive issues which arise during the conduct of such litigation and negotiations and shall take due and proper account of the interests of the Indemnified Party;

9.11.2 the Indemnifying Party shall not settle or compromise the Indemnity Claim without the Indemnified Party's prior written consent (not to be unreasonably withheld or delayed) and shall ensure that any settlement or compromise does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of the Indemnified Party;

9.11.3 the Indemnified Party shall not make any admissions or admit liability in relation to the Indemnity Claim or otherwise settle any Indemnity Claim without the written agreement of the Indemnifying Party; and

9.11.4 the Indemnified Party shall fully cooperate and assist the Indemnifying Party, at the Indemnifying Party's cost and expense, in relation to the Indemnity Claim (without limiting the extent of the Indemnity).

10. INSURANCE

10.1 Without prejudice to the allocation of liability detailed in clause 9, each Party shall at its own cost be solely responsible for taking out and maintaining in force during the term those policies of insurance required by law.

11. INTELLECTUAL PROPERTY

11.1 Subject to clause 11.2 neither Party shall acquire any right, title or interest in the other Party's Background IP.

11.2 The Customer grants to Fujifilm a [***] for the exclusive purpose of [***]. Customer [***].

11.3 All title to and all rights and interest in any Customer Foreground IP shall vest in Customer. Fujifilm hereby assigns to the Customer all title to and all rights and interest it owns in any Customer Foreground IP.

11.4 All title to and all rights and interest in any Fujifilm Foreground IP shall vest in Fujifilm. The Customer hereby assigns to Fujifilm all title to and all rights and interest it owns in any Fujifilm Foreground IP.

11.5 If requested to do so by the other Party, each Party shall at the expense of the requesting Party execute all documents and do all such further acts as the requesting Party may reasonably require to perfect the assignment under clause 11.3 or 11.4.

11.6 Fujifilm grants to Customer a [***] for the exclusive purpose of [***]. Fujifilm [***].

12. INTELLECTUAL PROPERTY INDEMNITY

12.1 Fujifilm shall fully Indemnify the Customer from and against all Liabilities incurred by the Customer or its Affiliates arising out of any third party claim that [***].

12.2 The Customer shall fully Indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Affiliates arising out of any third party claim that:

12.2.1 [***]; or

12.2.2 [***],

[***].

12.3 If a third party claim is made in accordance with clause 12.1 or 12.2 then the Indemnified Party may require the Indemnifying Party to prove that it has adequate financial means to pay out any amount finally awarded to such party by a competent court of law under the indemnity provisions provided for in those clauses (for example by way of set aside capital or insurance). If the Indemnifying Party cannot so prove it has the financial standing to meet its obligations with respect to the Indemnities under the applicable clause then the Indemnified Party has the option to terminate this Agreement on written notice. If Fujifilm exercises its option to terminate under this clause 12.3 then (without prejudice to the survival of the relevant Indemnity obligations) such termination shall be treated as a termination by Fujifilm under clause 15.1.

13. CONFIDENTIALITY

13.1 Each Party (the "**Receiving Party**") agrees with the other (the "**Disclosing Party**"):

13.1.1 to keep the Disclosing Party's Confidential Information confidential;

13.1.2 not to access or use the Disclosing Party's Confidential Information save for complying with its obligations under this Agreement or, if applicable, any confidentiality disclosure agreement then in force between the Parties;

13.1.3 not to disclose the Disclosing Party's Confidential Information to a third party other than to the Receiving Party's:

(c) Affiliates;

(d) officers and employees and those of its Affiliates that need to know the Confidential Information for the purpose of performing its obligations under this Agreement;

(e) contractors and sub-contractors, professional advisers, consultants and agents and those of its Affiliates who are engaged to advise that Party in connection with the Program or this Agreement; and

(f) any other person to whom the Disclosing Party agrees in writing that Confidential Information may be disclosed in connection with the Program,

the "**Authorized Third Parties**".

13.2 The Receiving Party shall procure that each of the Authorized Third Parties keeps the Disclosing Party's Confidential Information confidential in accordance with this clause 13 and shall remain fully liable to the Disclosing Party for any act or omission of any of the Authorized Third Parties.

13.3 The Receiving Party shall within [***] of receipt of the Disclosing Party's written request (including after termination of this Agreement):

13.3.1 deliver up to the Disclosing Party all items and copies of all or any Confidential Information of the Disclosing Party;

13.3.2 expunge and/or make irretrievable all Confidential Information of the Disclosing Party from any computer or other similar device in which it is stored and, if further requested, certify in writing signed by an authorized representative that it has done the same (provided that this clause 13.3.2 shall not apply to automatically archived electronic files or electronic back-ups made in the ordinary course of business, on secured central servers, which cannot reasonably be deleted and such electronic files shall be retained subject to the obligations of confidence set out in this clause 13); and

13.3.3 destroy all hard copies of notes, analyses or memoranda containing the Disclosing Party's Confidential Information (and, if further requested, certify in writing signed by an authorized representative that it has done the same)

provided that the Receiving Party shall be entitled to retain copies of the Confidential Information to enable it to monitor its obligations under this Agreement or which is required to be maintained by Applicable Laws or a Regulatory Authority subject always to the obligations of confidence under this Agreement.

13.4 Confidential Information shall not include information which:

13.4.1 is, or becomes, generally available to the public other than as a direct or indirect result of the information being disclosed by the Receiving Party or its Authorized Third Parties in breach of this Agreement (except that any compilation of otherwise public information in a form not publicly known shall still be treated as Confidential Information);

13.4.2 was available to the Receiving Party on a non-confidential basis prior to disclosure by the Disclosing Party;

13.4.3 was, is, or becomes available to the Receiving Party on a non-confidential basis from a person who, to the Receiving Party's knowledge, is not under any confidentiality obligation in respect of that information;

13.4.4 was lawfully in the possession of the Receiving Party before the information was disclosed by the Disclosing Party;

13.4.5 is developed by or for the Receiving Party independently of the information disclosed by the Disclosing Party;

13.4.6 is necessarily disclosed by the Receiving Party pursuant to a statutory or regulatory obligation, but then only to the extent of such required disclosure and save that the Receiving Party shall, to the extent it is lawful to do so, give prompt notice to the Disclosing Party of any such potential disclosure and allow the Disclosing Party a reasonable opportunity to limit such disclosure; or

13.4.7 the Disclosing Party and the Receiving Party agree in writing is not confidential.

13.5 If a Party concludes that a copy of this Agreement must be filed with the United States Securities Exchange Commission or other regulatory agency ("SEC") (or equivalent foreign agency or a securities exchange), such Party will use all reasonable efforts to provide the other Party with a copy of this Agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, and to provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions. The filing Party will take such other Party's reasonable comments into consideration before filing the Agreement.

14. CHANGE

14.1 If a party wishes to change any aspect of this Agreement or any Scope of Work then the parties shall agree any such changes in a change order drafted in Fujifilm's standard format and agreed in writing and signed by both parties (and such change shall be referred to as a "Change").

14.2 If there is a change to Applicable Law which comes into effect after the Effective Date that adversely affects, or is likely to adversely affect, production of Product by the Process when conducted in accordance with Fujifilm's standard operating procedures or methods, and within the declared constraints of the Facility then the Parties will enter into a Change to accommodate that change of Applicable Law, the cost of which shall be allocated as follows:

14.2.1 if the change to Applicable Law specifically relates to the Product, Process or Dedicated Equipment then [***]; and

14.2.2 if the change to Applicable Law relates to the Facility (including equipment other than Dedicated Equipment) as it is operated by Fujifilm for purposes of the Program then [***].

14.3 If Fujifilm decides to implement a Change to the Facility (including equipment other than Dedicated Equipment) without this being necessitated by changes in Applicable Law, then [***]

14.4 In determining the appropriate allocation of charges for a Change other than one initiated pursuant to clause 14.2 and 14.3, if not agreed by the parties then either party may refer the Change to the Joint Steering Committee that may offer a non-binding opinion on the allocation of costs. The Joint Steering Committee shall consider that Fujifilm will typically receive the benefit of [***], and the Customer will typically receive the benefit of [***]. Other improvements will be shared equitably as negotiated by the Joint Steering Committee.

14.5 If the Parties are unable to agree a Change to accommodate a change of Applicable Law, Fujifilm may terminate any affected Order (or part of it) or this Agreement without any liability to the Customer by giving written notice to the Customer if Fujifilm reasonably believes that it will be unable to carry out and complete such Order in accordance with this Agreement or any future purchase order (as the case may be) due to the change of Applicable Law.

15. TERMINATION AND CONSEQUENCES

15.1 Termination for cause: Either Party shall be entitled to terminate this Agreement (and all Orders made under it) immediately upon giving notice to the other if:

15.1.1 the other Party commits a material breach of this Agreement and such breach:

(a) is not capable of remedy (a breach shall be considered capable of remedy if the Party in breach can comply with the provision in question in all respects other than as to time of performance); or

(b) is capable of remedy, and the breaching Party fails to remedy the breach within a reasonable period after receipt of notice giving full particulars of the breach and requiring it to be remedied, provided, however, that such cure period shall be suspended during any time that a Party seeks resolution of a dispute as to whether an alleged material breach occurred pursuant to clause 17;

15.1.2 the other Party takes any step or action in connection with its entering administration, provisional liquidation or any composition or arrangement with its creditors (other than in relation to a solvent restructuring), being wound up (whether voluntarily or by order of the court, unless for the purpose of a solvent restructuring), having a receiver appointed to any of its assets or ceasing to carry on business or, if he step or action is taken in another jurisdiction, in connection with any analogous procedure in the relevant jurisdiction; or

15.2 Termination for change in Control of Fujifilm

15.2.1 The Customer may terminate this Agreement at any time by giving Fujifilm not less than 2 (two) years' prior written notice to Fujifilm if Fujifilm has a change in Control and the new Controlling entity is [***].

15.2.2 The right to terminate in clause 15.2.1 must be exercised by the Customer within [***] of the date the Customer is notified by Fujifilm of the change in Control of Fujifilm, after such period the right to terminate pursuant to clause 15.2.1 expires.

15.2.3 The Customer's rights in this clause 15.2 are without prejudice to any prior commitment to minimum purchase commitments for future years, which will continue to be due in accordance with clause 15.3.4.

15.3 Consequences of Termination

15.3.1 The termination of this Agreement shall be without prejudice to the rights and remedies of either Party which may have accrued up to the date of termination.

15.3.2 If the Customer terminates this Agreement in whole or in part pursuant to clause 2.3, 2.4 or 15.2, or Fujifilm terminates this Agreement under clauses 15.1, the Customer shall pay:

(a) the Charges for the Minimum Annual Quantity for each Production Year up to the date that the Customer has provided commitment;

(b) (if higher than the corresponding Minimum Annual Quantity) in respect of the [***] Half Years that follow the date of termination, the Charges for the actual forecast volume (based on the forecast applicable at the termination date), subject to adjustment to the lowest permitted variation to those forecast volumes, as detailed in clause 2.2 of Schedule 2,

together with, in each case, unpaid Pass Through Costs incurred prior to such termination. Fujifilm shall deliver all Product Ordered during the notice period in accordance with the terms of this Agreement.

15.3.3 On termination of this Agreement for any reason whatsoever:

(a) save as set out in clause 0 the relationship of the Parties shall cease and any rights or licenses granted under or pursuant to this Agreement shall cease to have effect save as (and to the extent) expressly provided for in this clause 15;

(b) the provisions of the following clauses together with any provision which expressly or by implication is intended to come into or remain in force on or after termination shall continue in full force and effect clauses 1, 8, 9, 0, 12, 13, 15, 17, 19, and 23; and

(c) the Customer shall immediately pay to Fujifilm all of Fujifilm's outstanding unpaid invoices and interest and, in respect of Batches and other services supplied (or would have been supplied but for termination) but for which no invoice has been submitted, Fujifilm may submit an invoice, which shall be payable immediately on receipt.

15.3.4 If Fujifilm terminates this Agreement under clause 15.1 or the Customer terminates this Agreement under clause 15.2 or the Customer terminates the Intermediate Product aspects of this Agreement pursuant to clause 2.4, then the Customer shall pay:

(a) the Charges for any Batch that, but for termination, would have been supplied pursuant to an Order placed prior to termination;

(b) the Charges for each Batch that the Customer has committed to (as detailed in Schedule 2) prior to termination (as may be adjusted in accordance with a Change addressing capacity expansion) (in any case including the Minimum Annual Quantities for each year);

(c) any [***] incurred prior to termination in respect of items that Fujifilm will no longer be able to use.

15.3.5 Technology Transfer.

(a) On termination of this Agreement with respect to the Products or the Intermediate Products Fujifilm shall transfer to the Customer copies of all documentation and all other records necessary for production of Products, or Intermediate Products as may apply, in a manner compliant with Applicable Law; provided, however, that Fujifilm may redact any portion of any such records that contain information not related to the Products or the Process.

(b) Fujifilm shall [***] enable the Customer to transfer manufacture of such Product after the date of termination, disclose to the Customer or a third party contract manufacturing organization, (i) [***] and (ii) upon reasonable notice cause its employees engaged in the manufacture of the Products to meet with representatives of the Customer, [***];

(c) if any Background IP of Fujifilm is incorporated into the Process and the Customer or a third party contract manufacturing organisation will require the Background IP to operate the Process, Fujifilm [***] a licence for the use of Background IP, [***];

(d) the cost of the technology transfer will be borne by [***] on the following basis (i) if the Customer terminates or Fujifilm terminates pursuant to clause 15.1, [***] will pay [***]; or (ii) if Fujifilm terminates for any other reason, [***] will pay [***].

16. FORCE MAJEURE

16.1 Subject to clause 16.2, neither Party shall be liable to the other for any delay or non-performance of its obligations under any this Agreement (except for the payment of money) arising from a Force Majeure Event.

16.2 If either Party is delayed or prevented from performing its obligations due to a Force Majeure Event such Party shall:

16.2.1 give notice of such Force Majeure Event to the other Party as soon as reasonably practical stating the commencement date and extent of such delay or prevention, the cause thereof and its estimated duration;

16.2.2 use reasonable endeavours to mitigate the effects of such Force Majeure Event; and

16.2.3 resume performance of its obligations as soon as reasonably practicable.

16.3 If the Force Majeure Event in question continues for more than [***] the Customer may give notice in writing to Fujifilm to terminate this Agreement. If the Force Majeure Event in question continues for more than [***] Fujifilm may give notice in writing to the Customer to terminate this Agreement. The notice to terminate must specify the termination date, which must not be less than [***] after the date on which the notice is given, and once such notice has been validly given, this Agreement will terminate on that termination date.

17. DISPUTE RESOLUTION

17.1 If there is a dispute in relation to or in connection with the QA Documents, such dispute shall be dealt with in accordance with the procedures set out in the Quality Agreement.

17.2 In respect of any dispute concerning this Agreement (other than a dispute in connection with the QA Documents) that is not resolved in the Joint Steering Committee the Parties shall seek to resolve the matter as follows:

17.2.1 if the dispute is not resolved within [***] of its referral to the Program Managers it shall be referred to the decision of Fujifilm's Chief Business Officer and the Customer's SVP of Product Supply; and

17.2.2 if the dispute is not resolved within [***] of its referral to Fujifilm's Chief Business Officer and the Customer's SVP of Product Supply it shall be referred to the decision of each Party's President or Chief Executive Officer (as applicable/appropriate).

17.3 If the dispute between the Parties is not resolved having applied the process set out at clause 17.2 then either Party may request that the dispute is settled under the Rules of Arbitration of the International Chamber of Commerce. The arbitration shall be held in [***], and English shall be the language used in the arbitration. The number of arbitrators shall be determined in accordance with the applicable rules.

17.4 Notwithstanding the provisions of this clause 17 either Party may commence or take proceedings or seek remedies before the courts or any other competent authority for interim, interlocutory or injunctive remedies in relation to this Agreement.

18. AUDIT

18.1 The Customer may carry out audits at the times, and in accordance with the terms, set out in the Quality Agreement provided that access by the Customer and/or its representatives to records, information and systems shall be on a supervised basis, subject to the Customer complying with the security and confidentiality requirements of Fujifilm to protect information which relates to anything other than the Programs and shall be limited to a maximum of [***]. During such audits Ascendis may be accompanied by potential business and/or licensing partners subject to reasonable prior notice to Fujifilm.

18.2 Audit access shall not be extended to Fujifilm's confidential records, including details of financial transactions and contracts with third parties that relate to this Agreement.

18.3 If Fujifilm is in material breach of this Agreement or if the Customer reasonably believes that Fujifilm is in material breach of this Agreement, the Customer may upon giving reasonable written notice to Fujifilm carry out an audit on the same basis as in clauses 18.1 and 18.2.

18.4 Additional audits (other than those carried out pursuant to clause 18.3), such as those required for FDA approvals or mock-Pre Approval Inspections, may be carried out on the same basis as in clauses 18.1 and 18.2 subject to (i) payment of Fujifilm's costs and expenses and the agreement of a commercial rate; and (ii) the Customer ensuring such audit will not delay or disrupt Fujifilm's operations at the Facility.

19. NOTICES

19.1 Subject to clause 19.2 the Parties may communicate with each other in any way that is normal in the course of their business.

19.2 Any notice given under clauses 2, 8, 9, 12, 13, 15, 16, 17, 18, 19.2, 20 or 21 shall only be effective if it is in writing, sent to a Party at its address or email address and for the attention of the individual, as set out in Schedule 2 (or such other address, email address or individual as that Party may notify the other in accordance with this clause 19) and is given in accordance with clauses 19.3 and 19.4 below.

19.3 Notice may be given by hand or sent by email, recorded delivery, registered post or airmail and will be deemed to have been duly served:

19.3.1 if delivered by hand, at the time and date of delivery;

19.3.2 if sent by email, at the time and date of sending;

19.3.3 If sent by reputable overnight courier (i.e., FedEx, UPS), at the time and date of delivery (as evidenced by tracking information);

19.3.4 if sent by recorded delivery or registered post, 48 (forty-eight) hours from the date of posting (such date as evidenced by postal receipt); and

19.3.5 if sent by registered airmail, five days from the date of posting,

provided that, where in the case of delivery by hand or transmission by email, such delivery or transmission occurs either after 4.00pm on a Business Day, or on a day other than a Business Day, service will be deemed to occur at 9.00am on the next Business Day.

19.4 In proving service of a notice it will be sufficient to prove that delivery was made or that the envelope containing the notice or document was properly addressed and posted (either by prepaid first class recorded delivery post or by prepaid airmail, as the case may be) or that no failed delivery message was received, as the case may be.

20. EXPORT CONTROLS, MODERN SLAVERY AND CORRUPTION

20.1 The Customer acknowledges that export and/or use of any Product may be subject to compliance with laws, rules and regulations of bodies having jurisdiction over such operations. If the export or use of any Products is so controlled, it is the responsibility of the Customer to obtain any such approval required by any applicable laws, rules or regulations.

20.2 Each Party shall endeavour to hold itself and its suppliers to the highest performance, ethical and compliance standards, including basic human rights, not engaging in any activity, practice or conduct which would constitute an offence under anti-slavery legislation in the United Kingdom or the U.S.A, encouraging fair and equal treatment for all persons, the provision of safe and healthy working conditions, respect for the environment, the adoption of appropriate management systems and the conduct of business in an ethical manner. In performing its duties under this Agreement, each Party acknowledges the value and importance of performance and ethical behaviour in its performance under this Agreement.

20.3 Each Party warrants that on the Effective Date, it, its directors, officers or employees have not offered, promised, given, authorized, solicited or accepted any undue pecuniary or other advantage of any kind (or implied that they will or might do any such thing at any time in the future) in any way connected with this Agreement and that it has taken reasonable measures to prevent subcontractors, agents or other third parties, subject to its control or determining influence, from doing so.

20.4 The Parties agree that, at all times in connection with and throughout the term of this Agreement, they will comply with and that they will take reasonable measures to ensure that their subcontractors, agents or other third parties will comply with all applicable anti-corruption legislation including the Bribery Act 2010, if applicable, or the Foreign Corrupt Practices Act 1977.

20.5 Each Party shall not do, or omit to do, any act that would cause one of the other Parties to be in breach of any relevant anti-corruption legislation including the Bribery Act 2010, if applicable, or the Foreign Corrupt Practices Act 1977.

21. ASSIGNMENT AND SUB-CONTRACTING

21.1 Either Party may assign or transfer all of its rights and responsibilities under this Agreement to:

21.1.1 an Affiliate provided that such Affiliate has reasonable financial creditworthiness; or

21.1.2 a purchaser of all or substantially all of the equity of the assigning party provided that such third party has reasonable financial creditworthiness; or

21.1.3 a purchaser of all or substantially all of assets to which this Agreement relates provided that such third party has reasonable financial creditworthiness; or

21.1.4 a third party to which the Customer has licensed, divested or otherwise transferred its interest in the Products,

but not otherwise without written consent of the other Party (such consent not to be unreasonably withheld or delayed) and provided that (a) the assignee agrees in writing to assume all obligations undertaken by its assignor in this Agreement and (b) in relation to assignment in part no such assignment shall relieve the assigning Party of responsibility for the performance of any of its obligations under this Agreement.

21.2 If a Party assigns or transfers all or any of its rights and responsibilities under clause 21.1 it shall immediately notify the other Party in writing.

21.3 Fujifilm may sub-contract all or any of its obligations under this Agreement [***].

22. GENERAL

22.1 Entire agreement: This Agreement contains all the terms which the Parties have agreed with respect to their subject matter and supersede all previous agreements and understandings between the Parties (whether oral or in writing) relating to such subject matter. Each Party acknowledges and agrees that it has not been induced to enter into this Agreement by a statement or promise which it does not contain. Each Party confirms that save as otherwise expressly set out in this Agreement, the other Party gives no warranties either in this Agreement or elsewhere in connection with the provision of the Programs. Nothing in this clause 22.1 shall exclude or limit a Party's liability for fraud, including fraudulent misrepresentation.

22.2 Third Party rights: Save as expressly set out in this Agreement, the Parties do not intend that any person who is not a Party to this Agreement shall have any right to enjoy the benefit or enforce any of the terms of this Agreement.

22.3 Variations: With the exception of Changes, which shall be subject to clause 0, no variation of this Agreement shall be valid unless in writing and signed by a duly authorized representative of each of the Parties. A Party is entitled assume that a representative of another Party is authorized to act on that Party's behalf if that individual is apparently or seemingly acting in the normal course of the business relationship. An exchange of emails shall not be capable of constituting an agreement to vary this Agreement.

22.4 Waiver: No failure or delay by a Party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it preclude or restrict the further exercise of that or any other right or remedy. The single or partial exercise by either Party of any right, power or remedy under this Agreement shall not in any circumstances preclude any other or further exercise of it, or the exercise of any right, power or remedy. A waiver by either Party of a breach of any provision of this Agreement shall not be considered as a waiver of a subsequent breach of the same or any other provision of this Agreement.

22.5 Severability: If any provision of this Agreement is found by any court or administrative body of competent jurisdiction to be invalid, illegal or unenforceable in any jurisdiction then it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible that provision shall be deemed to be omitted from this Agreement in so far as this Agreement relates to that jurisdiction and the validity and enforceability of that provision in other jurisdictions and the other provisions of this Agreement shall not be affected or impaired.

22.6 Counterparts: This Agreement may be executed in any number of counterparts. Either Party may enter into this Agreement by executing a counterpart and all the counterparts taken together will constitute one and the same agreement. This Agreement shall not be effective until each Party has signed one counterpart.

23. GOVERNING LAW

23.1 The formation, existence, construction, performance, validity and all aspects whatsoever of this Agreement or any term of it and any issues, disputes or claims arising out of or in connection with it (whether contractual or non-contractual in nature) shall be governed by, and construed in accordance with, [***] law and subject to clause 17.3 the Parties irrevocably submit to the jurisdiction of the courts of [***].

IN WITNESS of the above the Parties have signed this Agreement on the dates written on the Signature Page to be found after the schedules.

Schedule 1 Charges

1. **Batch Price**

1.1 The Batch Price for the Product is set out in the following table:

[***]

1.2 Notes relating to the above table:

[***]

1.3 The following are included / not included in the Batch Prices for Products:

1.3.1 Batch Prices include:

[***]

1.3.2 Batch Prices do not include:

[***]

1.4 The Batch prices for [***] is set out in the following table:

[***]

1.5 Notes relating to the above table:

1.5.1 **[***]**

1.6 The following are included / not included in the Batch Prices for [***]:

1.6.1 Batch Prices include:

[***]

1.6.2 Batch Prices do not include:

[***]

1.7 Reference to a "**Campaign Price**" is to the total of all applicable Batch Prices for a Campaign.

1.8 In respect of each Campaign of Product Customer shall pay:

1.8.1 **[***]**

1.9 Payments pertaining to clauses [***] above shall be [***], while payments pertaining to clause [***] above shall be [***].

1.10 The Customer agrees that for every Production Year it will pay for the Minimum Annual Quantity even if it places Orders for fewer Batches of the Product than the number of Batches of Product provided for in the Minimum Annual Quantity for that Production Year. Fujifilm will invoice the Customer for any such shortfall in Batches of the Product [***]. In case where the likelihood of such a shortfall has been shared in the JSC, Fujifilm will make Commercially Reasonable Efforts to utilize the Facility during the period during which manufacture of the Batch was intended to take place ("Mitigation Measures") through the acquisition of new business. Fujifilm shall reduce the invoice by a sum equivalent to [***].

1.11 In respect of each Campaign of [***] Reagent the Customer shall pay:

1.11.1 [***]

2. **Charges for [***] and Sub-Contracted Work**

2.1 In addition to the Batch Price for each Batch, the Customer will pay Fujifilm for Consumables, [***] (the "**Pass Through Costs**") at a rate of [***]. The Pass Through Costs shall be payable when invoiced by Fujifilm in accordance with the provisions of paragraphs 2.3 and 2.4 below. [***]

2.2 [***]

2.3 Invoices for raw materials and consumables will be issued as follows:

[***]

On completion of each Campaign, Fujifilm shall calculate the [***] in respect of such Batch [***].

3. **Customer Deliverables and other materials on termination**

3.1 Within [***] of termination of this Agreement, the Customer shall notify Fujifilm what (if any) Customer Deliverables the Customer wishes Fujifilm to deliver to the Customer and delivery of those Customer Deliverables shall take place in accordance with clause 7. If the Customer does not give any such notification to Fujifilm within [***] of termination of this Agreement, Fujifilm may destroy such samples and/or cell banks without further notice [***].

Provided that the Customer has paid for any Materials in relation to which payment is due, Fujifilm shall deliver Materials to Customer in accordance with clause 7.

4. **Price Increases**

4.1 The Batch Price specified in paragraph 1 of this Schedule 1 shall be adjusted [***] in an amount equal to [***]

4.2 [***]

Schedule 2 Forecasting and Orders

1. **Minimum and Maximum Orders**

1.1. The Minimum Annual Quantity is the number of Batches of Product that the Customer agrees to pay for during the applicable Production Year as set out in paragraph 1.3 of this Schedule 2 or otherwise determined in accordance with paragraph 1.9 of Schedule 1.

1.2. The Maximum Annual Quantity is the maximum number of Batches of Product that Fujifilm agrees it can manufacture for the Customer during the applicable Production Year.

1.3. The Minimum Annual Quantity and Maximum Annual Quantity for the initial Production Years are as follows:

PRODUCTION YEAR	MINIMUM ANNUAL QUANTITY*	[***]	MAXIMUM ANNUAL QUANTITY*
2020	[***]	[***]	[***]
2021	[***]	[***]	[***]
2022 and beyond	As per the forecast mechanism in paragraph 2 of this Schedule 2		As per the forecast mechanism in paragraph 2 of this Schedule 2[***]

* Batches refers to Batches of Product ([***])

[***]

1.4. The Minimum Annual Quantity and Maximum Annual Quantity for each Production Year following the period specified in the above table will [***].

1.5. Fujifilm shall reserve capacity of [***] in addition to the Minimum Annual Quantity. If this additional capacity is not required by the Customer it shall not form part of the Minimum Annual Quantity and will not be factored into the calculation of any shortfall volume in a Production Year (pursuant to clause 8.2).

2. **Forecasting**

2.1. By [***] (each a "**Forecast Date**"), the Customer shall provide to Fujifilm a forecast of its requirements for Batches of Product for the [***] following the Forecast Date, broken down into 6 (six) month increments (each being a "**Half Year**", the first Half Year commencing on the Forecast Date being known as the 1st Half Year and subsequent half Years being numbered accordingly). A reference in this paragraph 2 to the previous forecast shall mean the forecast issued at the immediately previous Forecast Date.

2.2. Each forecast shall be subject to the following principles:

2.2.1. the forecast for [***] shall be binding and the subject of an Order made pursuant to paragraph 3;

2.2.2. from the Forecast Date that follows [***], the forecast for [***] shall not deviate from the corresponding period in the previous forecast ([***]) by more than [***];

2.2.3. from the Forecast Date that follows [***], the forecast for [***] shall not deviate from the corresponding period in the previous forecast ([***]) by more than [***];

2.2.4. prior to the Forecast Date that follows [***]:

2.2.4.1. the forecast for [***] shall not deviate from the corresponding period in the previous forecast ([***]) by more than [***]; and

2.2.4.2. the forecast for [***] shall not deviate from the corresponding period in the previous forecast ([***]) by more than [***];

2.2.5. there shall be no restrictions on deviations in forecasts in [***].

2.3. [***]

2.4. The Parties have agreed certain Minimum Annual Volumes, which are detailed in clauses 4.1. No Forecast may be submitted for a quantity of Batches in a period that is less than the corresponding Minimum Annual Quantity.

2.5. Once a Forecast has been issued to Fujifilm it may not be varied unless the Parties agree a Change.

2.6. If, in any Production Year, the Customer would like Fujifilm to manufacture a number of Batches in excess of the Maximum Annual Quantity it shall notify Fujifilm in writing and the Parties will promptly discuss such request. Fujifilm may agree (in a Change) to manufacture an agreed number of Batches in excess of the Maximum Annual Quantity if it has sufficient manufacturing capacity to do so ([***]) but nothing in this Agreement shall oblige Fujifilm to supply Batches in excess of the Maximum Annual Quantity in any Production Year unless it has agreed to do so in a Change.

3. **Ordering**

3.1. The Customer will issue a written purchase order (the "**Order**") for the Batches of Product it requires to be supplied on the Forecast Date for all Batches of Product included in [***] of the forecast. The first Order placed by the Customer shall commit the Customer to all Batches of Product in [***] of the forecast.

3.2. Fujifilm shall acknowledge Orders in writing within [***] of receipt.

3.3. Once acknowledged by Fujifilm Orders are non-cancellable by either Party.

3.4. Notwithstanding paragraphs 3.1 to 3.3, if the Customer fails to submit an Order for part or all of a binding component of a forecast (which may include binding minimum volume commitments), the Customer shall be deemed to have placed such Order in line with the timescales set out in paragraph 3.1.

3.5. Orders, Order acknowledgements and/or other similar documentation submitted by either Party in conducting activities under this Agreement are for administration purposes only and (notwithstanding any statement or terms stated within such documentation) shall not add to or modify the terms of this Agreement.

3.6. Each order placed by the Customer shall be for [***] ([***]), save that it is acknowledged that the Customer may place Orders for the Intermediate Product recombinant human growth hormone (hGH) or for inclusion bodies for [***].

Schedule 3 Addresses for Notice

FDBK:

Contact: [***]

Address: Fujifilm Diosynth Biotechnologies, Belasis Avenue, Billingham, TS23 1LH, England

Nominated email address: [***]

Copied to:

Contact: [***]

Address: Fujifilm Diosynth Biotechnologies, Belasis Avenue, Billingham, TS23 1LH, England

Nominated email address: [***]

Customer:

Contact: [***]

Address: Tuborg Boulevard 12, DK-2900 Hellerup, Denmark

Nominated email address: [***]

Copied to:

Contact: [***]

Address: Tuborg Boulevard 12, DK-2900 Hellerup, Denmark

Nominated email address: [***]

Schedule 4 Customer Deliverables

Supply the [***] in the volumes and by the dates required by Fujifilm to fulfil its commitments to the Customer, and to the specification required as part of the Process. The required amount of [***] will be delivered to Fujifilm no later than [***] before the Product manufacture. [***]

Schedule 5 Storage Agreement

THIS AGREEMENT is effective from the date of the last signature and is between:

(1) **FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED** (a company registered in England under number 5803359) whose registered address is Belasis Avenue, Billingham TS23 1LH ("**Fujifilm**"); and

(2) The Customer.

TERMS AND CONDITIONS OF THIS AGREEMENT

1. **Interpretation**. The following words or phrases shall have the meaning given to them in the Schedule: "**Customer**"; "**Stored Items**"; "**Charges**"; and "**Facility**". The term "**Storage Services**" shall mean the storage by Fujifilm of the Stored Items in the agreed conditions following adequate procedures, using equipment with adequate safeguards (e.g. alarms and emergency power supply), and all activities ancillary to that storage including, without limitation, taking items into storage and releasing items to Customer.

2. **Term.** This Storage Agreement shall come into effect on the Effective Date of the Commercial Supply Agreement.

3. **Storage Services**. Fujifilm shall store the Stored Items at the Facility(ies), provided that in each case the location of the Stored Items meets the storage conditions specified in the Schedule. Each Facility shall be compliant with cGMP if applicable. Provision of the Storage Services does not grant Customer exclusivity over any area of a Facility. Fujifilm shall determine, acting reasonably, the distribution of Stored Items between the Facilities and may specify that Stored Items be moved between Facilities in which case clause 5 shall apply.

4. **Delivery of Stored Items.** If the Stored Items are not in Fujifilm's control as at the Effective Date then the Stored Items will be delivered by Customer [***] the Facility (Incoterms 2010). The Stored Items will be delivered to Customer [***] the Facility (Incoterms 2010). [***]

5. **Transportation of Stored Items between Facilities**. Unless redistribution of the Stored Items is specifically requested by Customer, Fujifilm shall be responsible for arranging transportation of the Stored Items between the Facilities during the term of this Agreement [***] subject to clause 7.

6. **Packaging of Stored Items.** Unless the Stored Items are used by Fujifilm in the manufacture of Product(s), Fujifilm will package the Stored Items ready for transportation and/or delivery [***] and in accordance with Customer's reasonable written instructions.

7. **Risk in Stored Items**. Risk in the Stored Items shall [***].

8. **Ownership of Stored Items and Insurance**. The Stored Items shall be the property of Customer unless: (i) expressly stated to the contrary in the Schedule; or (ii) the Stored Items contain Fujifilm proprietary intellectual property.

9. **Charges**. In consideration of the Storage Services, Customer shall pay to Fujifilm the Charges according to the schedule.

10. **Value Added Tax (VAT)**. If VAT applies to Fujifilm's services under this Agreement, [***]. If there is any retrospective application of VAT on Fujifilm's services that have already been performed and invoiced on a VAT exempt basis, or an increased amount of VAT being due as a result of a change in the VAT rate payable or the VAT treatment of the services or a change in the law or practice or interpretation of existing legislation, Fujifilm may invoice Customer for such amounts and Customer will pay those invoices in accordance with clause 9.

11. **Termination**. This Storage Agreement shall terminate if and when the Supply Agreement terminates.

12. **Consequences of Termination or Expiry**. At the end of this Agreement: (i) Customer shall immediately pay to Fujifilm all outstanding sums whether or not yet invoiced; (ii) Fujifilm shall notify Customer in writing of any Stored Items that remain in the Facilities and, if Customer does not request delivery ([***] at the applicable Facility) within [***] of the notice, Fujifilm may at its discretion dispose of the items [***]; (iii) any provision of this Agreement which expressly or impliedly has effect after termination will continue to be enforceable notwithstanding termination. Termination of this Agreement shall not affect either Party's accrued right and obligations at the date of termination.

13. **Limitations of Liability**. Save that nothing in this Agreement shall limit or exclude any liability which Fujifilm is not permitted to limit or exclude by law; it is agreed that [***]

14. **Confidentiality**. Each Party agrees with the other to keep confidential the other Party's Confidential Information and not to use the other's Confidential Information save for complying with its obligations under this Agreement. No disclosure may be made to third parties unless (and only to the extent that): (i) to service providers or professional advisors under a duty of confidentiality; and (ii) it is necessary due to statutory or regulatory obligation. "**Confidential Information**" shall mean the fact of and terms of this Agreement and any other information that is identified as being of a confidential or proprietary nature or that would be regarded as confidential by a reasonable business person.

15. **Notices**. Any notice required to be served by either Party to the other shall only be effective if it is in writing and sent to a Party at its registered office for the attention of [***].

16. **Third Parties**. No term of this Agreement shall be enforceable under the Contracts (Rights of Third Parties) Act 1999 by a person who is not a Party to it.

17. **Law and Jurisdiction**. This Agreement is governed by [***] law and any dispute arising out of the Agreement shall be subject to the non-exclusive jurisdiction of the [***] courts.

SCHEDULE TO STORAGE AGREEMENT

1. Customer details

The "**Customer**" is:

ASCENDIS PHARMA A/S (a company registered in Denmark) whose registered address is Tuburg Boulevard 12, DK-2900 Hellerup, Denmark ("**Customer**").

2. Stored Items, agreed storage conditions, and charges

The following are the Items which may be stored under this Storage Agreement together with the applicable Charges:

[***]

3. Facilities

The following are the location of the storage facilities used by Fujifilm (each being a "**Facility**"):

[***]

4. Charges

At the end of [***], Fujifilm shall prepare a statement specifying for each Stored Item how many units were stored and for how long, and shall issue an invoice to Customer for the total amount, to be paid by Customer within [***].

5. **Inventory reports**

Fujifilm will provide a [***] overview summarising the quantities of the various items stored.

Signature Page of Commercial Supply Agreement

SIGNED for and on behalf of **FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED**:

Signature: /s/ Paul Found

Name: Paul Found

Title: COO

Date: 09 Jan 2019

SIGNED for and on behalf of **ASCENDIS PHARMA A/S**:

Signature: /s/ Michael Wolff Jensen

Name: Michael Wolff Jensen

Title: Senior Vice President

Date: 18-Dec-2018

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

EXECUTION VERSION

SHAREHOLDERS AGREEMENT

THIS SHAREHOLDERS AGREEMENT (this "**Agreement**") is made and entered into as of November 7, 2018 by and among:

(1) VISEN Pharmaceuticals, a company established under the laws of Cayman Islands (the "**Company**"),

(2) Ascendis Pharma Endocrinology Division A/S, a company established under the Laws of Denmark, Ascendis Pharma Bone Diseases A/S, a company established under the Laws of Denmark, Ascendis Pharma Growth Disorders A/S, a company established under the Laws of Denmark and Ascendis Pharma A/S, a company organized under the laws of Denmark (collectively, "**Ascendis**"),

(3) Vivo Plenilune IX Limited, a company established under the Laws of Cayman Islands ("**Vivo Capital**"),

(4) Sofinnova Venture Partners IX, L.P., a limited partnership established under the Laws of the State of Delaware ("**Sofinnova**," together with Ascendis and Vivo Capital, each an "**Investor**", and collectively the "**Investors**"),

(5) A private company limited by shares and a wholly owned subsidiary of the Company to be established under the laws of Hong Kong, which will accede to this Agreement as a Party upon its establishment (the "**HK Subsidiary**"), and

(6) A limited liability company and a wholly owned subsidiary of the HK Subsidiary to be established under the laws of the People's Republic of China (excluding Hong Kong, Macao and Taiwan, the "**PRC**"), which will accede to this Agreement as a Party upon its establishment (the "**WFOE**").

The Company, the HK Subsidiary and the WFOE are referred to collectively herein as the "**Group Companies**", and each, a "**Group Company**". Each of the forgoing parties is referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

A. The Company and the Investors have entered into a Series A Preferred Share Purchase Agreement dated as of the date hereof (the "**Share Purchase Agreement**"), under which, among other things, the Company shall issue and allot certain number of series A preferred shares of the Company, par value US$0.0001 per share (the "**Series A Preferred Shares**") to the Investors, at the Closings.

B. In connection with the consummation of the transactions contemplated by the Share Purchase Agreement, the parties hereto desire to enter into this Agreement and the other Transaction Documents for the governance, management and operations of the Group Companies and for the rights and obligations among the holders of Series A Preferred Shares and the Company.

C. The Share Purchase Agreement provides that the execution and delivery of this Agreement by the parties shall be a condition precedent to the consummation of the transactions contemplated under the Share Purchase Agreement.

D. Unless otherwise defined in this Agreement, capitalized terms used in this Agreement shall have the meanings set forth in the Share Purchase Agreement.

NOW, THEREFORE, in consideration of the foregoing recitals, the mutual promises hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. INFORMATION RIGHTS; BOARD REPRESENTATION.

1.1. Information and Inspection Rights.

(a) Information Rights. The Company covenants and agrees that, commencing on the date of this Agreement, the Company shall deliver to each holder of the Series A Preferred Shares holding no less than ten percent (10%) of the Company's total issued and outstanding Series A Preferred Shares:

(i) within thirty (30) days after the end of each fiscal quarter, unaudited quarterly consolidated financial statements and other documents reflecting the business activities and performance (including but not limited to tax filings and management reports) for such quarter and analysis of the Group Companies' business operation;

(ii) within forty-five (45) days after the end of each fiscal year, unaudited annual consolidated financial statements for such fiscal year and implementation of the budget for such fiscal year; and

(iii) within four (4) months after the end of each fiscal year, audited annual consolidated financial statements for such fiscal year, audited by the accounting firms reasonably acceptable to Ascendis and Vivo Capital (the "**Major Investors**").

Promptly upon the written request by any holder of Series A Preferred Shares representing no less than ten percent (10%) of the Company's total issued and outstanding Series A Preferred Shares, such other information as such holder of Series A Preferred Shares shall reasonably request from time to time, including, without limitation, an up-to-date capitalization table, the most recent version of the investment agreements, documents relating to subsequent financing and a copy of the official articles of association or other constitutional documents of the Group Companies. In addition, the Company shall provide to Ascendis such information and financial statements of the Group Companies and provide access to personnel reasonably requested by Ascendis in order for Ascendis to timely comply with applicable disclosure and financial and tax reporting requirements. The rights set forth above shall be collectively referred to as the "**Information Rights**".

All financial statements to be provided to such holder of Series A Preferred Shares pursuant to this Section 1.1(a) shall be in English and shall include an income statement, a balance sheet, a cash flow statement for the relevant period as well as for the fiscal year to-date and shall be prepared in conformance with the PRC Generally Accepted Accounting Principles (the "**PRC GAAP**") with respect to the Group Companies in the PRC, or the International Financial Reporting Standards (the "**IFRS**") with respect to the Company and the Group Company outside of the PRC.

(b) Inspection Rights. The Company further covenants and agrees that, commencing on the date of this Agreement, for so long as Ascendis or Vivo Capital continues to hold Series A Preferred Shares or Ordinary Shares issued or issuable upon conversion thereof representing no less than ten percent (10%) of the Company's total outstanding share capital on fully-diluted and as-converted basis, each such Investor shall have (i) the right to inspect facilities, records and books of the Group Companies at any time during regular working hours upon reasonable prior notice to the Company, (ii) the right to discuss the business, operations and conditions of the Group Companies with their respective directors, officers, employees, accountants, legal counsel, financial advisors, and investment bankers, and (iii) the right to dispatch auditing personnel of its own or hire independent auditors to audit the books and records of the Group Companies as needed (the "**Inspection Rights**"). Such auditing personnel or independent auditors shall have access to all financial statements, financial records, original receipts and other documents of the Group Companies. Such audit shall not be conducted more than two (2) times per year. The Company shall, and shall cause the Group Companies to provide necessary assistance for such audit. The Investor that hires an independent auditor shall bear the cost of such auditor.

1.2. Board of Directors and Observers. The Amended and Restated Memorandum and Articles of Association of the Company (the "**Restated Articles**") shall provide that the board of directors of the Company (the "**Board**") shall consist of five (5) members, which number of members shall not be changed except pursuant to an amendment to the Restated Articles. Effective from the date hereof,

(a) Ascendis shall be entitled to appoint and remove one (1) director, who shall initially be Jan Moller Mikkelsen (the "**Ascendis Director**"),

(b) Vivo Capital shall be entitled to appoint and remove two (2) directors, who shall initially be Shan FU and Dandan DONG, (each, a "**Vivo Capital Director,**" and collectively, the "**Vivo Capital Directors,**" together with the Ascendis Director, the "**Series A Directors**") and shall be entitled to appoint one (1) such member to any committee of the Board,

(c) the person then serving as the Chief Executive Officer of the Company shall be appointed as a director of the Company, and

(d) one (1) independent person who is not employed by any Group Company, who is not Affiliated with any Group Company or any Investor and who is mutually acceptable to the Major Investors.

Vivo Capital shall also be entitled to appoint one (1) observer (the "**Observer**") to attend all meetings of the Board in a non-voting, observer capacity, and to receive concurrently with the members of the Board all notices of Board meetings (and copies of materials distributed at or in connection with Board meetings). A meeting of directors is duly constituted for all purposes if at the commencement of the meeting there are present in person or by alternate such number of directors not less than a majority of the directors of the Company, which directors in each case shall include each of the Series A Directors, provided, however, that if a requisite quorum is not achieved based on the failure to attend such meeting by any Series A Director, then the quorum at such rescheduled meeting shall be a majority of the Directors then in office. The Company shall reimburse the directors and the Observer for all reasonable out-of-pocket expenses incurred in connection with attending any meetings of the Board and any committee thereof.

1.3. Board of Directors of Subsidiaries. The size and composition of the board of directors of any subsidiary of the Company, whether now in existence or formed in the future (the "**Subsidiaries**"), which is wholly owned directly or indirectly by the Company, shall mirror the Board.

1.4. Voting Agreement. Each Party agrees that it shall vote all of its Shares (or give shareholders' consent) in such manner that gives effect to the provisions of this Agreement, including without limitation to cause the Board to be constituted in accordance with Section 1.2.

1.5. Termination. The provisions set forth under this Section 1 shall terminate upon the earlier to occur of (i) a firm-commitment underwritten initial public offering by the Company of its Ordinary Shares or a reverse merger of the Company with a listed company, on a reputable securities exchange in the United States, Hong Kong or PRC (excluding the National Equities Exchange And Quotations of the PRC), or any other jurisdiction, including without limitations, the New York Stock Exchange or the Nasdaq Global Market in the United States and the Main Board of the Hong Kong Stock Exchange, with a per share price of at least US$[***] (subject to adjustments for share dividends, splits, combinations, recapitalization and similar events) and net proceeds to the Company of at least US$[***] (the "**Qualified Initial Public Offering**"), and (ii) the closing of a Liquidation Event (as defined in the Restated Articles).

2. REGISTRATION RIGHTS.

2.1. Applicability of Rights. The Holders (as defined below) shall be entitled to the following rights with respect to any proposed public offering of the Company's Ordinary Shares in the United States and shall be entitled to reasonably equivalent or analogous rights with respect to any other offering of the Company's securities in the Hong Kong SAR or any other jurisdiction in which the Company undertakes to publicly offer or list such securities for trading on a recognized securities exchange.

2.2. Definitions. For purposes of this Section 2:

(a) Registration. The terms "**register**," "**registered**," and "**registration**" refer to a registration effected by filing a registration statement which is in a form which complies with, and is declared effective by the SEC (as defined below) in accordance with, the Securities Act of 1933, as amended to date (the "**Securities Act**").

(b) Registrable Securities. The term "**Registrable Securities**" means: (1) any Ordinary Shares of the Company issued or issuable pursuant to conversion of any issued and outstanding shares of Series A Preferred Shares, excluding any Ordinary Shares issued upon conversion of the Series A Preferred Shares pursuant to Article 36A of the Company's Restated Articles (Special Mandatory Conversion), (2) any Ordinary Shares issued (or issuable upon the conversion or exercise of any warrant, right or other security which is issued) as a dividend or other distribution with respect to, or in exchange for or in replacement of, any Series A Preferred Shares described in clause (1) of this subsection (b), and (3) any

other Ordinary Shares of the Company owned or hereafter acquired by the Investors. Notwithstanding the foregoing, "**Registrable Securities**" shall exclude any Registrable Securities sold by a person in a transaction in which rights under this Section 2 are not validly assigned in accordance with this Agreement, and any Registrable Securities which are sold in a registered public offering under the Securities Act or analogous statute of another jurisdiction, or sold pursuant to Rule 144 promulgated under the Securities Act or analogous rule of another jurisdiction.

(c) Registrable Securities Then Outstanding. The number of shares of "**Registrable Securities then Outstanding**" shall mean the number of Ordinary Shares of the Company that are Registrable Securities and are then issued and outstanding, issuable upon conversion of Series A Preferred Shares then issued and outstanding, or issuable upon conversion or exercise of any warrant, right or other security then outstanding.

(d) Holder. For purposes of this Section 2, the term "**Holder**" means any person owning or having the rights to acquire Registrable Securities or any permitted assignee of record of such Registrable Securities to whom rights under this Section 2 have been duly assigned in accordance with this Agreement.

(e) Form F-3. The term "**Form F-3**" means such respective form under the Securities Act or any successor registration form under the Securities Act subsequently adopted by the SEC which permits inclusion or incorporation of substantial information by reference to other documents filed by the Company with the SEC.

(f) SEC. The term "**SEC**" or "**Commission**" means the U.S. Securities and Exchange Commission.

(g) Registration Expenses. The term "**Registration Expenses**" shall mean all expenses incurred by the Company in complying with Sections 2.3, 2.4 and 2.5 hereof, including, without limitation, all registration and filing fees, printing expenses, fees, and disbursements of counsel for the Company, reasonable fees and disbursements, not to exceed US$30,000, of one special counsel for all the Holders, "blue sky" fees and expenses, fees and expenses charged by share registrar and depository agent and the expense of any special audits incident to or required by any such registration (but excluding the compensation of regular employees of the Company which shall be paid in any event by the Company).

(h) Selling Expenses. The term "**Selling Expenses**" shall mean all underwriting discounts and selling commissions applicable to the sale of Registrable Securities pursuant to Sections 2.3, 2.4 and 2.5 hereof.

(i) Exchange Act. The term "**Exchange Act**" shall mean the Securities Exchange Act of 1934, as amended, and any successor statute.

2.3. Demand Registration.

(a) Request by Holders. If the Company shall, at any time after the earlier of (i) three (3) years after the Initial Closing or (ii) six (6) months following the taking effect of a registration statement for the initial underwritten public offering of the securities of the Company (the "**IPO**"), receive a written request from the Holders of at least [***] percent ([***]%) of the Registrable Securities then Outstanding that the Company file a registration statement under the Securities Act on any internationally recognized exchange that is acceptable to such requesting Holders pursuant to this Section 2.3 covering the registration of the Registrable Securities then Outstanding subject to a minimum offering size of US$15,000,000, then the Company shall, within ten (10) Business Days of the receipt of such written request, give written notice of such request (the "**Request Notice**") to all Holders, and use its best efforts to effect, as soon as practicable, the registration under the Securities Act of all Registrable Securities that the Holders request to be registered and included in such registration by written notice given by such Holders to the Company within twenty (20) days after receipt of the Request Notice, subject only to the limitations of this Section 2.3; provided that the Company shall not be obligated to effect any such registration if the Company has, within the six (6) month period preceding the date of such request, already effected a registration under the Securities Act pursuant to this Section 2.3 or Section 2.5 or in which the Holders had an opportunity to participate pursuant to the provisions of Section 2.4, other than a registration from which the Registrable Securities of the Holders have been excluded (with respect to all or any portion of the Registrable Securities the Holders requested be included in such registration) pursuant to the provisions of Section 2.4(a). The Company shall be obligated to effect no more than two (2) Registration pursuant to this Section 2.3. A registration shall not be counted as "effected" for purposes of this Section 2.3(a) until such time as the applicable registration statement has been declared effective by the SEC, unless the Initiating Holders (as defined below) withdraw their request for such registration, elect not to pay the registration expenses therefor, and forfeit their right to one demand registration statement pursuant to Section 2.6, in which case such withdrawn registration statement shall be counted as "effected" for purposes of this Section 2.3(a). For purposes of this Agreement, reference to registration of securities under the Securities Act and the Exchange Act shall be deemed to mean the equivalent registration in a jurisdiction other than the United States as designated by such Holders, it being understood and agreed that in each such case all references in this Agreement to the Securities Act, the Exchange Act and rules, forms of registration statements and registration of securities thereunder, U.S. law and the SEC, shall be deemed to refer, to the equivalent statutes, rules, forms of registration statements, registration of securities and laws of and equivalent government authority in the applicable non-U.S. jurisdiction.

(b) Underwriting. If the Holders initiating the registration request under this Section 2.3 (the "**Initiating Holders**") intend to distribute the Registrable Securities covered by their request by means of an underwriting, then they shall so advise the Company as a part of their request made pursuant to this Section 2.3 and the Company shall include such information in the Request Notice. In such event, the right of any Holder to include its Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting (unless otherwise mutually agreed by a majority in interest of the Initiating Holders and such Holder) to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall enter into an underwriting agreement in customary form with the managing underwriter or underwriters selected for such underwriting by the Holders of a majority of the Registrable Securities being registered and reasonably acceptable to the Company. Notwithstanding any other provision of this Section 2.3, if the underwriter(s) advise(s) the Company in writing that marketing factors require a limitation of the number of securities to be underwritten, then the Company shall so advise all Holders of Registrable Securities which would otherwise be registered and underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be reduced as required by the underwriter(s) and allocated among the Holders of Registrable Securities on a pro rata basis according to the number of Registrable Securities then

Outstanding held by each Holder requesting registration (including the Initiating Holders); provided, however, that the number of shares of Registrable Securities to be included in such underwriting and registration shall not be reduced unless all other securities are first entirely excluded from the underwriting and registration including, without limitation, all shares that are not Registrable Securities and are held by any other person, including, without limitation, any person who is an employee, officer or director of the Company or any subsidiary of the Company; provided further, that at least twenty-five percent (25%) of Registrable Securities requested by the Holders to be included in such underwriting and registration shall be so included. If any Holder disapproves of the terms of any such underwriting, such Holder may elect to withdraw therefrom by written notice to the Company and the underwriter(s), delivered at least ten (10) business days prior to the effective date of the registration statement. Any Registrable Securities excluded or withdrawn from such underwriting shall be excluded and withdrawn from the registration.

2.4. Piggyback Registrations.

(a) The Company shall notify all Holders of Registrable Securities in writing at least thirty (30) days prior to filing any registration statement under the Securities Act for purposes of effecting a public offering of securities of the Company (including, but not limited to, registration statements relating to secondary offerings of securities of the Company, but excluding registration statements relating to any employee benefit plan or a corporate reorganization), and shall afford each such Holder an opportunity to include in such registration statement all or any part of the Registrable Securities then held by such Holder. Each Holder desiring to include in any such registration statement all or any part of the Registrable Securities held by it shall within twenty (20) days after receipt of the above-described notice from the Company, so notify the Company in writing, and in such notice shall inform the Company of the number of Registrable Securities such Holder wishes to include in such registration statement. If a Holder decides not to include all of its Registrable Securities in any registration statement thereafter filed by the Company, such Holder shall nevertheless continue to have the right to include any Registrable Securities in any subsequent registration statement or registration statements as may be filed by the Company with respect to offerings of its securities, all upon the terms and conditions set forth herein. No Holder of Registrable Securities shall be granted piggyback registration rights superior to those of the Holders of the Series A Preferred Shares without the consent in writing of the Holders of at least fifty percent (50%) of the Registrable Securities.

(b) Underwriting. If a registration statement under which the Company gives notice under this Section 2.4 is for an underwritten offering, then the Company shall so advise the Holders of Registrable Securities. In such event, the right of any such Holder's Registrable Securities to be included in a registration pursuant to this Section 2.4 shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their Registrable Securities through such underwriting shall enter into an underwriting agreement in customary form with the managing underwriter or underwriters selected for such underwriting. Notwithstanding any other provision of this Agreement but subject to Section 2.13, if the managing underwriter(s) determine(s) in good faith that marketing factors require a limitation of the number of shares to be underwritten, then the managing underwriter(s) may exclude shares from the registration and the underwriting, and the number of shares that may be included in the registration and the underwriting shall be allocated, first, to the Company, second, to each of the Holders requesting inclusion of their

Registrable Securities in such registration statement on a pro rata basis based on the total number of shares of Registrable Securities then held by each such Holder, and third, to holders of other securities of the Company; provided, however, that the right of the underwriter(s) to exclude shares (including Registrable Securities) from the registration and underwriting as described above shall be restricted so that (i) the number of Registrable Securities included in any such registration is not reduced below twenty percent (20%) of the aggregate number of shares of Registrable Securities for which inclusion has been requested; and (ii) all shares that are not Registrable Securities and are held by any other person, including, without limitation, any person who is an employee, officer or director of the Company (or any subsidiary of the Company) shall first be excluded from such registration and underwriting before any Registrable Securities are so excluded. If any Holder disapproves of the terms of any such underwriting, such Holder may elect to withdraw therefrom by written notice to the Company and the underwriter(s), delivered at least ten (10) business days prior to the effective date of the registration statement. Any Registrable Securities excluded or withdrawn from such underwriting shall be excluded and withdrawn from the registration.

(c) Not Demand Registration. Registration pursuant to this Section 2.4 shall not be deemed to be a demand registration as described in Section 2.3 above. There shall be no limit on the number of times the Holders may request registration of Registrable Securities under this Section 2.4.

2.5. Form F-3. If at any time when it is eligible to use a Form F-3 registration statement the Company shall receive from the Holders of at least thirty percent (30%) of the Registrable Securities then Outstanding a written request or requests that the Company effect a registration on Form F-3 and any related qualification or compliance with respect to all or a part of the Registrable Securities owned by such Holder or Holders, then the Company will:

(a) Notice. Promptly give written notice of the proposed registration and the Holder's or Holders' request therefor, and any related qualification or compliance, to all other Holders of Registrable Securities; and

(b) Registration. As soon as practicable, effect such registration and all such qualifications and compliances as may be so requested and as would permit or facilitate the sale and distribution of all or such portion of such Holders or Holders' Registrable Securities as are specified in such request, together with all or such portion of the Registrable Securities of any other Holder or Holders joining in such request as are specified in a written request given within twenty (20) days after the Company provides the notice contemplated by Section 2.5(a); provided, however, that the Company shall not be obligated to effect any such registration, qualification or compliance pursuant to this Section 2.5:

(i) if the Holders, together with the holders of any other securities of the Company entitled to inclusion in such registration, propose to sell Registrable Securities and such other securities (if any) at an aggregate price to the public of less than US$5,000,000;

(ii) if the Company shall furnish to the Holders a certificate signed by the President or Chief Executive Officer of the Company stating that in the good faith judgment of the Board, it would be materially detrimental to the Company and its shareholders for such Form F-3 registration to be effected at such time, in which event the Company shall have the right to defer the filing of the Form F-3 registration statement no more than once during any twelve (12) month period for a period of not more than sixty (60) days after receipt of the request of the Holder or Holders under this Section 2.5; provided that the Company shall not register any of its other shares during such sixty (60) day period; A registration right under this Section 2.5 shall not be deemed to have been exercised until such deferred registration shall have been effected;

(iii) if the Company has, within the twelve (12) month period preceding the date of such request, already effected one (1) registration on Form F-3;

(iv) if the Company has, within the twelve (12) month period preceding the date of such request, already effected two (2) registrations under the Securities Act other than a registration from which the Registrable Securities of Holders have been excluded (with respect to all or any portion of the Registrable Securities the Holders requested be included in such registration) pursuant to the provisions of Sections 2.3(b) and 2.4 (a); or

(v) in any particular jurisdiction in which the Company would be required to qualify to do business or to execute a general consent to service of process in effecting such registration, qualification or compliance.

Subject to the foregoing, the Company shall file a Form F-3 registration statement covering the Registrable Securities and other securities so requested to be registered as soon as practicable after receipt of the request or requests of the Holders.

(c) Not Demand Registration. Form F-3 registrations shall not be deemed to be demand registrations as described in Section 2.3 above. Except as otherwise provided herein, there shall be no limit on the number of times the Holders may request registration of Registrable Securities under this Section 2.5.

2.6. Expenses. All Registration Expenses incurred in connection with any registration pursuant to Sections 2.3, 2.4 or 2.5 (but excluding Selling Expenses) shall be borne by the Company. Each Holder participating in a registration pursuant to Sections 2.3, 2.4 or 2.5 shall bear such Holder's proportionate share (based on the total number of shares sold in such registration other than for the account of the Company) of all Selling Expenses or other amounts payable to underwriter(s) or brokers, in connection with such offering by the Holders. Notwithstanding the foregoing, the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Section 2.3 if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered, unless the Holders of a majority of the Registrable Securities then Outstanding agree that such registration constitutes the use by the Holders of one (1) demand registration pursuant to Section 2.3; provided further, however, that if at the time of such withdrawal, the Holders have learned of a material adverse change in the condition, business, or prospects of the Company not known to the Holders at the time of their request for such registration and have withdrawn their request for registration with reasonable promptness after learning of such material adverse change, then the Holders shall not be required to pay any of such expenses and such registration shall not constitute the use of a demand registration pursuant to Section 2.3.

2.7. Obligations of the Company. Whenever required to effect the registration of any Registrable Securities under this Agreement the Company shall, as expeditiously as reasonably possible:

(a) Registration Statement. Prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its best efforts to cause such registration statement to become effective, and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to ninety (90) days or, in the case of Registrable Securities registered under Form F-3 in accordance with Rule 415 under the Securities Act or a successor rule, until the distribution contemplated in the registration statement has been completed; provided, however, that (i) such ninety (90) day period shall be extended for a period of time equal to the period any Holder refrains from selling any securities included in such registration at the request of the underwriter(s), and (ii) in the case of any registration of Registrable Securities on Form F-3 which are intended to be offered on a continuous or delayed basis, such ninety (90) day period shall be extended, if necessary, to keep the registration statement effective until all such Registrable Securities are sold.

(b) Amendments and Supplements. Prepare and file with the SEC such amendments and supplements to such registration statement and the prospectus used in connection with such registration statement as may be necessary to comply with the provisions of the Securities Act with respect to the disposition of all securities covered by such registration statement.

(c) Prospectuses. Furnish to the Holders such number of copies of a prospectus, including a preliminary prospectus, in conformity with the requirements of the Securities Act, and such other documents as they may reasonably request in order to facilitate the disposition of the Registrable Securities owned by them that are included in such registration.

(d) Blue Sky. Use its best efforts to register and qualify the securities covered by such registration statement under such other securities or “blue sky” laws of such jurisdictions as shall be reasonably requested by the Holders, provided that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act.

(e) Underwriting. In the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement in usual and customary form, with the managing underwriter(s) of such offering. Each Holder participating in such underwriting shall also enter into and perform its obligations under such an agreement.

(f) Notification. Notify each Holder of Registrable Securities covered by such registration statement at any time when a prospectus relating thereto is required to be delivered under the Securities Act of (i) the issuance of any stop order by the SEC in respect of such registration statement, or (ii) the happening of any event as a result of which the prospectus included in such registration statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing.

(g) Opinion and Comfort Letter. Furnish, at the request of any Holder requesting registration of Registrable Securities, on the date that such Registrable Securities are delivered to the underwriter(s) for sale, if such securities are being sold through underwriters, or, if such securities are not being sold through underwriters, on the date that the registration statement with respect to such securities becomes effective, (i) an opinion, dated as of such date, of the counsel representing the Company for the purposes of such registration, in form and substance as is customarily given to underwriters in an underwritten public offering and reasonably satisfactory to a majority in interest of the Holders requesting registration, addressed to the underwriters, if any, and to the Holders requesting registration of Registrable Securities and (ii) letters dated as of (x) the effective date of the registration statement covering such Registrable Securities and (y) the closing date of the offering, from the independent certified public accountants of the Company, in form and substance as is customarily given by independent certified public accountants to underwriters in an underwritten public offering and reasonably satisfactory to a majority in interest of the Holders requesting registration, addressed to the underwriters, if any, and to the Holders requesting registration of Registrable Securities.

2.8. Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to Sections 2.3, 2.4 or 2.5 that the selling Holders shall furnish to the Company such information regarding themselves, the Registrable Securities held by them and the intended method of disposition of such securities as shall be required to timely effect the Registration of their Registrable Securities.

2.9. Indemnification. In the event any Registrable Securities are included in a registration statement under Sections 2.3, 2.4 or 2.5:

(a) By the Company. To the extent permitted by law and the Restated Articles, the Company will indemnify and hold harmless each Holder, its partners, officers, directors, legal counsel, any underwriter (as defined in the Securities Act) for such Holder and each person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any losses, claims, damages, or liabilities (joint or several) to which they may become subject under the Securities Act, the Exchange Act, or other United States federal or state law, insofar as such losses, claims, damages, or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (collectively a "**Violation**"):

(i) any untrue statement or alleged untrue statement of a material fact contained in such registration statement, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto;

(ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or

(iii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any United States federal or state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any United States federal or state securities law in connection with the offering covered by such registration statement;

and the Company will reimburse each such Holder, its partner, officer, director, legal counsel, underwriter or controlling person for any legal or other expenses reasonably incurred by them, as such expenses are incurred, in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the indemnity agreement contained in this subsection 2.9(a) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the consent of the Company (which consent shall not be unreasonably withheld), nor shall the Company be liable in any such case for any such loss, claim, damage, liability or action to the extent that it arises out of or is based upon a Violation which occurs in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder, partner, officer, director, legal counsel, underwriter or controlling person of such Holder.

(b) By Selling Holders. To the extent permitted by law, each selling Holder will, if Registrable Securities held by Holder are included in the securities as to which such registration qualifications or compliance is being effected, indemnify and hold harmless the Company, each of its directors, each of its officers who has signed the registration statement, each person, if any, who controls the Company within the meaning of the Securities Act, any underwriter and any other Holder selling securities under such registration statement or any of such other Holder's partners, directors, officers, legal counsel or any person who controls such Holder within the meaning of the Securities Act or the Exchange Act, against any losses, claims, damages or liabilities (joint or several) to which the Company or any such director, officer, legal counsel, controlling person, underwriter or other such Holder, partner or director, officer or controlling person of such other Holder may become subject under the Securities Act, the Exchange Act or other United States federal or state law, insofar as such losses, claims, damages or liabilities (or actions in respect thereto) arise out of or are based upon any Violation, in each case to the extent (and only to the extent) that such Violation occurs in reliance upon and in conformity with written information furnished by such Holder expressly for use in connection with such registration; and each such Holder will reimburse any legal or other expenses reasonably incurred by the Company or any such director, officer, controlling person, underwriter or other Holder, partner, officer, director or controlling person of such other Holder in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the indemnity agreement contained in this subsection 2.9(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld; and provided, further, that in no event shall any indemnity under this Section 2.9(b) together with any amount contributed pursuant to Section 2.9(d) below exceed the net proceeds (net of any Selling Expenses paid by such Holder) received by such Holder in the registered offering out of which the applicable Violation arises, except in the case of willful misconduct or fraud by such Holder.

(c) Notice. Promptly after receipt by an indemnified party under this Section 2.9 of notice of the commencement of any action (including any governmental action), such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.9, deliver to the indemnifying party a written notice of the commencement thereof and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party shall have the right to retain its own counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential conflict of interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action shall relieve such indemnifying party of liability to the indemnified party under this Section 2.9 to the extent the indemnifying party is prejudiced as a result thereof, but the omission to so deliver written notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 2.9.

(d) Contribution. In order to provide for just and equitable contribution to joint liability under the Securities Act in any case in which either (i) any indemnified party makes a claim for indemnification pursuant to this Section 2.9 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Section 2.9 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any indemnified party in circumstances for which indemnification is provided under this Section 2.9; then, and in each such case, the indemnified party and the indemnifying party will contribute to the aggregate losses, claims, damages or liabilities to which they may be subject (after contribution from others) in such proportion so that a Holder (together with its related persons) is responsible for the portion represented by the percentage that the public offering price of its Registrable Securities offered by and sold under the registration statement bears to the public offering price of all securities offered by and sold under such registration statement, and the Company and other selling Holders are responsible for the remaining portion. The relative fault of the indemnifying party and of the indemnified party shall be determined by a court of law by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case: (A) no Holder will be required to contribute any amount in excess of the net proceeds to such Holder from the sale of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement; and (B) no person or entity guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person or entity who was not guilty of such fraudulent misrepresentation.

(e) Survival; Consents to Judgments and Settlements. The obligations of the Company and Holders under this Section 2.9 shall survive until the fifth (5th) anniversary of the completion of any offering of Registrable Securities in a registration statement, regardless of the expiration of any statutes of limitation or extensions of such statutes. No indemnifying party, in the defense of any such claim or litigation, shall, except with the consent of each indemnified party, consent to entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect to such claim or litigation.

2.10. No Registration Rights to Third Parties. Without the prior written consent of the holders of at least sixty percent (60%) of the Series A Preferred Shares then outstanding, the Company covenants and agrees that it shall not grant, or cause or permit to be created, for the benefit of any person or entity any registration rights of any kind (whether similar to the demand, "piggyback" or Form F-3 registration rights described in this Section 2, or otherwise) relating to any securities of the Company which are senior to, or on a parity with, those granted to the Holders of Registrable Securities.

2.11. Rule 144 Reporting. With a view to making available to the Holders the benefits of certain rules and regulations of the SEC which may at any time permit the sale of the Registrable Securities to the public without registration or pursuant to a registration on Form F-3, after such time as a public market exists for the Ordinary Shares, the Company agrees to:

(a) Make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act, at all times after the effective date of the first registration under the Securities Act filed by the Company for an offering of its securities to the general public;

(b) File with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements); and

(c) So long as a Holder owns any Registrable Securities, to furnish to such Holder forthwith upon request (i) a written statement by the Company as to its compliance with the reporting requirements of Rule 144 (at any time after ninety (90) days after the effective date of the Company's initial public offering), the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements), or its qualification as a registrant whose securities may be resold pursuant to Form F-3 (at any time after it so qualifies), (ii) a copy of the most recent annual or quarterly report of the Company, and (iii) such other reports and documents of the Company as a Holder may reasonably request in availing itself of any rule or regulation of the SEC that permits the selling of any such securities without registration or pursuant to Form F-3.

2.12. Market Stand-Off. Each party agrees that, so long as it holds any voting securities of the Company, upon request by the Company or the underwriters managing the initial public offering of the Company's securities, it will not sell or otherwise transfer or dispose of any securities of the Company held immediately before the effective date of the registration statement for such offering (other than those permitted to be included in the registration and other transfers to Affiliates permitted by law) without the prior written consent of the Company or such underwriters, as the case may be, for a period of time specified by the representative of the underwriters not to exceed 180 days from the effective date of the registration statement covering such initial public offering or the pricing date of such offering as may be requested by the underwriters. The Company shall use commercially reasonable efforts to take all steps to shorten such lock-up period. The foregoing provision of this Section 2.12 shall not apply to the sale of any securities of the Company to an underwriter pursuant to any underwriting agreement, and shall only be applicable to the Holders if all officers and directors of the Group Companies and all shareholders owning more than five percent (5%) of the Company's outstanding Ordinary Shares (on an as-converted basis) are subject to the same restrictions, and if the Company or any underwriter releases any other shareholder from his, her or its sale restrictions so undertaken, then each Holder shall be notified prior to such release and shall itself be simultaneously released to the same proportional extent. The Company shall require all future acquirers of the Company's securities to execute prior to a Qualified Initial Public Offering a market stand-off agreement containing substantially similar provisions as those contained in this Section 2.12.

2.13. Termination. The registration rights in this Section 2 shall terminate upon the earliest to occur of (i) the closing of a Liquidation Event; (ii) such time as Rule 144 or another similar exemption under the Securities Act or other applicable securities laws is available for the sale of all of such Holder's shares without registration; and (iii) the third anniversary of the Qualified Initial Public Offering.

3. RIGHT OF PARTICIPATION.

3.1. General. Each holder of Series A Preferred Shares, including each holder of Series A Preferred Shares to which rights under this Section 3 have been duly assigned in accordance with Section 5 (hereinafter referred to as a "**Participation Rights Holder**"), shall have the preemptive right to purchase such Participation Rights Holder's Pro Rata Share (as defined below), of all (or any part) of any New Securities (as defined in Section 3.3) that the Company may from time to time issue after the date of this Agreement (the "**Right of Participation**").

3.2. Pro Rata Share. Subject to Section 2.3(iii) of the Share Purchase Agreement, a Participation Rights Holder's "**Pro Rata Share**" for purposes of the Right of Participation is the ratio of (a) the number of Ordinary Shares (calculated on a fully-diluted and as-converted basis) held by such Participation Rights Holder, to (b) the total number of Ordinary Shares of the Company then outstanding (calculated on a fully-diluted and as-converted basis) immediately prior to the issuance of the New Securities giving rise to the Right of Participation.

3.3. New Securities. "**New Securities**" shall mean any Series A Preferred Shares, Ordinary Shares or other voting shares of the Company and rights, options or warrants to purchase such Series A Preferred Shares, Ordinary Shares and securities of any type whatsoever that are, or may become, convertible or exchangeable into such Series A Preferred Shares, Ordinary Shares or other voting shares, provided, however, that the term "**New Securities**" shall not include the Exempted Securities (as defined in the Company's Amended and Restated Memorandum of Association).

3.4. Procedures.

(a) First Participation Notice. In the event that the Company proposes to undertake an issuance of New Securities (in a single transaction or a series of related transactions), it shall give to each Participation Rights Holder written notice of its intention to issue New Securities (the "**First Participation Notice**"), describing the amount and type of New Securities, the price and the general terms upon which the Company proposes to issue such New Securities. Each Participation Rights Holder shall have twenty (20) Business Days from the date of receipt of any such First Participation Notice (the "**First Participation Period**") to agree in writing to purchase such Participation Rights Holder's Pro Rata Share of such New Securities for the price and upon the terms and conditions specified in the First Participation Notice by giving written notice to the Company and stating therein the quantity of New Securities to be purchased (not to exceed such Participation Rights Holder's Pro Rata Share). If any Participation Rights Holder fails to so agree in writing within such twenty (20) Business Days period to purchase such Participation Rights Holder's full Pro Rata Share of an offering of New Securities, then such Participation Rights Holder shall forfeit the right hereunder to purchase that part of its Pro Rata Share of such New Securities that it did not agree to purchase.

(b) Second Participation Notice; Oversubscription. If any Participating Rights Holder fails or declines to exercise its Right of Participation in accordance with subsection (a) above, the Company shall promptly give notice (the "**Second Participation Notice**") to other Participating Rights Holders who exercised their Right of Participation (the "**Right Participants**") in accordance with subsection (a) above. Each Right Participant shall have ten (10) Business Days from the date of receipt of the Second Participation Notice (the "**Second Participation Period**") to notify the Company of its desire to purchase more than its Pro Rata Share of the New Securities, stating the number of the additional New Securities it proposes to buy (the "**Additional Number**"). If, as a result thereof, such oversubscription exceeds the total number of the remaining New Securities available for purchase, each oversubscribing Right Participant will be cut back by the Company with respect to its oversubscription to that number of remaining New Securities equal to the lesser of (x) the Additional Number and (y) the product obtained by multiplying (i) the number of the remaining New Securities available for subscription by (ii) a fraction, the numerator of which is the number of Ordinary Shares (calculated on a fully-diluted and as-converted basis) held by such oversubscribing Right Participant and the denominator of which is the total number of Ordinary Shares (calculated on a fully-diluted and as-converted basis) held by all the oversubscribing Right Participants.

(c) Each Right Participant who exercises its Right of Participation hereunder by delivering aforesaid notice shall be obligated to buy such number of New Securities in accordance with the terms of Section 3.4 and the Company shall so notify the Right Participants within ten (10) Business Days following the date of the Second Participation Notice. The transaction in connection with the New Securities shall be consummated within forty-five (45) days after the expiration of the Second Participation Period.

3.5. Failure to Exercise. Upon the expiration of the Second Participation Period, the Company shall have ninety days (90) days thereafter to sell the New Securities described in the First Participation Notice (with respect to the remaining New Securities) at the same or higher price and upon non-price terms not materially more favorable to the purchasers thereof than specified in the First Participation Notice, provided that the prospective purchaser of such New Securities shall comply with this Agreement and the Restated Articles, as maybe amended from time to time. In the event that the Company has not issued and sold such New Securities within such ninety days (90) day period, then the Company shall not thereafter issue or sell any New Securities without again first offering such New Securities to the Participation Rights Holders pursuant to this Section 3.

3.6. Termination. The provisions set forth under this Section 3 shall terminate upon the earlier to occur of (i) the closing of a Liquidation Event; and (ii) immediately prior to the consummation of the Qualified Initial Public Offering.

4. TRANSFER RESTRICTIONS.

4.1. Certain Definitions. For purposes of this Section 4, "**Ordinary Shares**" means (i) the Company's outstanding Ordinary Shares, (ii) the Ordinary Shares issued or issuable upon conversion of the Company's outstanding Series A Preferred Shares, (iii) the Ordinary Shares issuable upon exercise of outstanding options or warrants and (iv) the Ordinary Shares issuable upon conversion of any outstanding convertible securities; "**Series A Preferred Shareholder**" means the holder of Series A Preferred Shares of the Company;

"**Ordinary Shareholder**" means a holder of any ordinary share of the Company other than Series A Preferred Shareholders; and "**Shareholder**" means a Series A Preferred Shareholder or an Ordinary Shareholder.

4.2. Series A Preferred Shareholder's Right of First Refusal. Subject to Section 4.4 of this Agreement, if any Shareholder proposes to directly or indirectly sell, assign, pledge, hypothecate, transfer, or otherwise encumber or dispose of in any way or otherwise grant any interest or right ("**Transfer**") with respect to all or any part of any interest in any Ordinary Shares held by it to any third party (each, a "**Selling Shareholder**"), then such Selling Shareholder shall promptly give written notice (the "**Transfer Notice**") to the Company and each non-selling Series A Preferred Shareholder (the "**Non-Selling Shareholders**") prior to such Transfer. The Transfer Notice shall describe in reasonable detail the proposed Transfer including, without limitation, the number of Ordinary Shares to be Transferred (the "**Offered Shares**"), the nature of such Transfer, the consideration to be paid, and the name and address of each prospective purchaser or transferee. The Non-Selling Shareholders may exercise their right of first refusal with respect to the Offered Shares as follows:

(a) Option of the Series A Preferred Shareholders.

(i) Each Non-Selling Shareholder shall have an option for a period of twenty (20) Business Days from receipt of the Transfer Notice (the "**Series A Preferred Shareholders' First Refusal Period**") to elect to purchase the Offered Shares at the same price and subject to the same terms and conditions as described in the Transfer Notice (the "**Series A Preferred Shareholders' Right of First Refusal**"). Each Non-Selling Shareholder may exercise the Series A Preferred Shareholders' Right of First Refusal and purchase all or any portion of the Offered Shares by notifying the Selling Shareholder, the Company and each other Non-Selling Shareholder in writing (the "**Series A Preferred Shareholders' First Refusal Notice**") before expiration of Series A Preferred Shareholders' First Refusal Period as to the number of shares that it wishes to purchase. The Series A Preferred Shareholders' First Refusal Notice shall set forth the number of Offered Shares that such Non-Selling Shareholder wishes to purchase, which amount shall not exceed the First Refusal Allotment (as defined below) of such Non-Selling Shareholder.

(ii) In the event any Non-Selling Shareholder elects not to purchase its First Refusal Allotment of the Offered Shares available under Section 4.2(a)(i) within the Series A Preferred Shareholders' First Refusal Period, then the Selling Shareholder shall promptly give written notice (the "**Series A Preferred Shareholders' Overallotment Notice**") to each Series A Preferred Shareholder that has elected to purchase all of its First Refusal Allotment of the Offered Shares (each a "**Fully Participating Series A Preferred Shareholder**"), which notice shall set forth the number of remaining Offered Shares not purchased by the other Non-Selling Shareholders ("**Series A Preferred Shareholders' Overallotment Shares**"), and shall offer the Fully Participating Series A Preferred Shareholders the right to acquire its First Refusal Allotment of the Series A Preferred Shareholders' Overallotment Shares. Each Fully Participating Series A Preferred Shareholder shall have five (5) Business Days after receipt of the Series A Preferred Shareholders' Overallotment Notice (the "**Series A Preferred Shareholders' Overallotment Period**") to deliver a written notice to the Selling Shareholder (the "**Participating Series A Preferred Shareholders' Overallotment Notice**") of its election to purchase its First Refusal Allotment of the Series A Preferred Shareholders' Overallotment Shares on the same terms and conditions as set forth in the Transfer Notice, which such Participating Series A Preferred Shareholders' Overallotment Notice shall also indicate the maximum number of the Series A Preferred Shareholders' Overallotment Shares that such Fully Participating Series A Preferred Shareholder will purchase in the event that any other Fully Participating Series A Preferred Shareholder elects not to purchase its First Refusal Allotment of the Series A Preferred Shareholders' Overallotment Shares.

(b) First Refusal Allotment. Each Non-Selling Shareholder shall have the right to purchase that number of the Offered Shares or Series A Preferred Shareholders' Overallotment Shares, as the case may be (the "**First Refusal Allotment**"), equivalent to the product obtained by multiplying the aggregate number of the Offered Shares or Series A Preferred Shareholders' Overallotment Shares, as the case may be, by a fraction, the numerator of which is the number of Ordinary Shares (on an as-converted basis) held by such Non-Selling Shareholder at the time of the transaction and the denominator of which is the total number of Ordinary Shares (on an as-converted basis) owned by all Non-Selling Shareholders at the time of the transaction who have the right of first refusal to purchase the applicable shares and have elected to participate in such right of first refusal purchase. A Non-Selling Shareholder shall not have a right to purchase any of the Offered Shares or Series A Preferred Shareholders' Overallotment Shares, as applicable, unless it exercises its right of first refusal within the Series A Preferred Shareholders First Refusal Period or the Series A Preferred Shareholders' Overallotment Period, as applicable, to purchase up to all of its First Refusal Allotment of the Offered Shares or Series A Preferred Shareholders' Overallotment Shares, as applicable.

(c) Purchase Price and Payment. The purchase price for the Offered Shares to be purchased by the Non-Selling Shareholders exercising their right of first refusal will be the price set forth in the Transfer Notice, but will be payable as set forth below. If the purchase price in the Transfer Notice includes consideration other than cash, the cash equivalent value of the non-cash consideration will be as previously determined by the Board in good faith (including affirmative votes of the Series A Directors) or by a third party appraisal institution engaged by the Board, which determination will be binding upon the Company, the Selling Shareholder and the Non-Selling Shareholders, absent fraud or error. The transaction shall be closed within forty-five (45) days following the date of the Transfer Notice and the payment of the purchase price shall be made by wire transfer or check as directed by the Selling Shareholder.

(d) Expiration Notice. Within five (5) days after the expiration of the Series A Preferred Shareholders' Overallotment Period, the Company will give written notice (the "**First Refusal Expiration Notice**") to the Selling Shareholder and the Non-Selling Shareholders specifying either (i) that all of the Offered Shares were subscribed by the Non-Selling Shareholders exercising their rights of first refusal, or (ii) that the Non-Selling Shareholders have not subscribed for all of the Offered Shares in which case the First Refusal Expiration Notice will specify the Co-Sale Pro Rata Portion (as defined below) of the remaining Offered Shares for the purpose of the co-sale right of the holders of the Series A Preferred Shares described in the Section 4.3 below.

(e) Rights of a Selling Shareholder. If any Non-Selling Shareholder exercises its right of first refusal to purchase the Offered Shares, then, upon the date the notice of such exercise is given by the Non-Selling Shareholder, the Selling Shareholder will have no further rights as a holder of such Offered Shares except the right to receive payment for such Offered Shares from such Non-Selling Shareholder in accordance with the terms of this Agreement, and the Selling Shareholder will forthwith cause all certificate(s) evidencing such Offered Shares to be surrendered to the Company for cancellation and deliver to the Company a duly executed share transfer in respect of the Offered Shares to be transferred to such Non-Selling Shareholder, and the Company shall update its register of members accordingly.

4.3. Series A Preferred Shareholder's Co-Sale Right. In the event that the Non-Selling Shareholders have not exercised their right of first refusal with respect to any or all of the Offered Shares, then the remaining Offered Shares not subscribed for under the right of first refusal pursuant to Section 4.2 above shall be subject to co-sale rights under this Section 4.3 and each Series A Preferred Shareholder who have not exercised any of its right of first refusal with respect to the Offered Shares shall have the right, exercisable upon written notice to the Selling Shareholder, the Company and each other Series A Preferred Shareholder (the "**Co-Sale Notice**") within twenty (20) Business Days after receipt of First Refusal Expiration Notice (the "**Co-Sale Right Period**"), to participate in such sale of the Offered Shares on the same terms and conditions as set forth in the Transfer Notice. The Co-Sale Notice shall set forth the number of Ordinary Shares (on as-converted basis) that such participating Series A Preferred Shareholder wishes to include in such sale or transfer, which amount shall not exceed the Co-Sale Pro Rata Portion (as defined below) of such Series A Preferred Shareholder. To the extent one or more of the Series A Preferred Shareholder exercise such right of participation in accordance with the terms and conditions set forth below, the number of Ordinary Shares that such Selling Shareholder may sell in the transaction shall be correspondingly reduced. The co-sale right of each Series A Preferred Shareholder shall be subject to the following terms and conditions:

(a) Co-Sale Pro Rata Portion. Each Series A Preferred Shareholder may sell all or any part of that number of Ordinary Shares held by it that is equal to the product obtained by multiplying (x) the aggregate number of the Offered Shares subject to the co-sale right hereunder by (y) a fraction, the numerator of which is the number of Ordinary Shares (on an as-converted basis) owned by such Series A Preferred Shareholder at the time of the sale or transfer and the denominator of which is the combined number of Ordinary Shares (on an as-converted basis) at the time owned by all Series A Preferred Shareholders who elect to exercise their co-sale rights (if any Series A Preferred Shareholder does not elect to exercise the co-sale right to the full extent then its Ordinary Shares (on as-converted basis) for calculation in the denominator shall be proportionately reduced) and the Selling Shareholder ("**Co-Sale Pro Rata Portion**").

(b) Transferred Shares. Each participating Series A Preferred Shareholder shall effect its participation in the sale by promptly delivering to the Selling Shareholder for transfer to the prospective purchaser one or more certificates, in addition to a duly executed instrument of transfer which represent:

(i) the number of Ordinary Shares which such Series A Preferred Shareholder elects to sell;

(ii) that number of Series A Preferred Shares which is at such time convertible into the number of Ordinary Shares that such Series A Preferred Shareholder elects to sell; provided in such case that, if the prospective purchaser objects to the delivery of Series A Preferred Shares in lieu of Ordinary Shares, such Series A Preferred Shareholder shall convert such Series A Preferred Shares into Ordinary Shares and deliver Ordinary Shares as provided in subsection 4.3(b)(i) above. The Company agrees to make any such conversion concurrent with the actual transfer of such shares to the purchaser; or

(iii) a combination of the above.

(c) Payment to Series A Preferred Shareholder. The share certificate or certificates that the participating Series A Preferred Shareholder delivers to the Selling Shareholder pursuant to Section 4.3(b) shall be surrendered to the Company for cancellation and the register of members of the Company shall be updated in consummation of the sale of the Offered Shares pursuant to the terms and conditions specified in the Transfer Notice, and the Selling Shareholder shall concurrently therewith remit to such Series A Preferred Shareholder that portion of the sale proceeds to which such Series A Preferred Shareholder is entitled by reason of its participation in such sale. To the extent that any prospective purchaser or purchasers prohibits such assignment or otherwise refuses to purchase any shares or other securities from a Series A Preferred Shareholder exercising its co-sale right hereunder, the Selling Shareholder shall not sell to such prospective purchaser or purchasers any Ordinary Shares unless and until, simultaneously with such sale, the Selling Shareholder shall purchase such shares or other securities from such Series A Preferred Shareholder.

(d) Right to Transfer. To the extent the Series A Preferred Shareholders do not elect to purchase, or to participate in the sale of, any or all of the Offered Shares subject to the Transfer Notice, the Selling Shareholder may, not later than ninety (90) days following delivery to the Company and each of the Series A Preferred Shareholders of the Transfer Notice, conclude a transfer of the remaining Offered Shares covered by the Transfer Notice and not elected to be purchased by the Non-Selling Shareholders, which in each case shall be on substantially the same terms and conditions as those described in the Transfer Notice. In the event the Selling Shareholder does not consummate the sale of such Offered Shares within ninety (90) business days in accordance with this Section 4.3(d), the rights of the Series A Preferred Shareholders under Sections 4.2 and 4.3 shall be re-invoked and shall be applicable to each subsequent disposition of such Offered Shares by the Selling Shareholder until such rights lapse in accordance with the terms of this Agreement. The Selling Shareholders shall cause any prospective purchaser of such shares to comply with this Agreement and Restated Articles, as maybe amended from time to time. Any proposed transfer on terms and conditions which are materially different from those described in the Transfer Notice, as well as any subsequent proposed transfer of any Ordinary Shares by the Selling Shareholder, shall again be subject to the right of first refusal of the Non-Selling Shareholders and the co-sale right of the Series A Preferred Shareholder and shall require compliance by the Selling Shareholder with the procedures described in Sections 4.2 and 4.3 of this Agreement.

4.4. Permitted Transfers. Notwithstanding anything to the contrary contained herein, the right of first refusal and co-sale rights of the Series A Preferred Shareholder as set forth in Section 4.2 and Section 4.3 above and the transfer restrictions set forth in Section 4.5 below shall not apply to (a) any sale or transfer of Ordinary Shares to the Company pursuant to a repurchase right or right of first refusal held by the Company in the event of a termination (either voluntary or involuntary) of employment or consulting relationship; and (b) any transfer by an Ordinary Shareholder of Ordinary Shares held by such Ordinary Shareholder as of the date hereof to its Affiliates, to trusts for the benefit of such Ordinary Shareholder or such Ordinary Shareholder's parents, children or spouse, for bona fide estate planning purposes, provided that the Ordinary Shareholder continues to exercise effective control over said Ordinary Shares including voting rights (each transferee pursuant to the foregoing subsections (a) or (b), a "**Permitted Transferee**"); provided that adequate documentation therefor is provided to the Series A Preferred Shareholders to their satisfaction and that any such Permitted Transferee agrees in writing to be bound by this Agreement in place of the relevant transferor; provided, further, that such transferor shall remain liable for any breach by such Permitted Transferee of any provision hereunder.

4.5. Prohibited Transfers.

(a) Except for transfers by any Investor to its Controlled Affiliates, until the earlier of (i) the Qualified Initial Public Offering and (ii) second (2nd) anniversary of the Initial Closing, none of the Shareholders shall, without the prior written approval of the holders of [***] percent ([***]%) of the Series A Preferred Shares, Transfer through one or a series of transactions any Company securities held by him to any person.

(b) Any attempt by a party to sell or transfer any share of the Company in violation of this Section 4 shall be void and the Company hereby agrees it will not effect such a transfer nor will it treat any alleged transferee as the holder of such shares without the requisite written consent.

4.6. Restriction on Indirect Transfers. The Parties agree that the transfer restrictions set out in this Section 4 shall not be circumvented or otherwise avoided by the holding of any Equity Securities of the Company indirectly through a company or other entity that can itself be sold in order to dispose of an interest in the Equity Securities of the Company free of such restrictions. Any transaction or Transfer directly or indirectly of shares of a shareholder of the Company or of any company (or other entity) having control over such shareholder of the Company shall be treated as a transfer of the Equity Securities of the Company held by that Shareholder, and the provisions of this Agreement that apply in respect of the transfer of Equity Securities of the Company shall apply to such transfer.

4.7. Legend.

(a) Each certificate representing the Ordinary Shares shall be endorsed with the following legend:

"THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 OF THE UNITED STATES, AS AMENDED. THE SALE, PLEDGE, HYPOTHECATION OR TRANSFER OF THE SECURITIES REPRESENTED BY THIS CERTIFICATE IS SUBJECT TO CERTAIN RESTRICTIONS ON TRANSFER SET FORTH IN A SHAREHOLDERS AGREEMENT, A COPY OF WHICH MAY BE OBTAINED UPON WRITTEN REQUEST TO THE SECRETARY OF THE COMPANY."

(b) Each party agrees that the Company may instruct its transfer agent to impose transfer restrictions on the shares represented by certificates bearing the legend referred to in Section 4.7(a) above to enforce the provisions of this Agreement and the Company agrees to promptly do so. The legend shall be removed upon termination of the provisions of this Section 4.

4.8. Term. The provisions under this Section 4 shall terminate upon the earlier to occur of (i) the closing of a Liquidation Event; and (ii) immediately prior to the consummation of the Qualified Initial Public Offering.

5. ASSIGNMENT AND AMENDMENT.

5.1. Assignment and Amendment. Notwithstanding anything herein to the contrary:

(a) Information Rights; Registration Rights. The Information Rights and Inspection Rights under Section 1.1 may be assigned to any holder of Series A Preferred Shares, and the registration rights of the Holders under Section 2 may be assigned to any Holder or to any person acquiring Registrable Securities, in each case, in accordance with the terms of this Agreement; provided, however, that in either case no party may be assigned any of the foregoing rights unless the Company is given written notice by the assigning party, stating the name and address of the assignee and identifying the securities of the Company as to which the rights in question are being assigned; provided further, that any such assignee shall receive such assigned rights subject to all the terms and conditions of this Agreement, including without limitation the provisions of this Section 5.

(b) Right of Participation; Right of First Refusal; Co-Sale Right. The rights of each holder of Series A Preferred Shares under Section 3 and each holder of Series A Preferred Shares under Section 4 are fully assignable in connection with a transfer of shares of the Company by such holder of Series A Preferred Shares in accordance with the terms of this Agreement; provided, however, that no party may be assigned any of the foregoing rights unless the Company is given written notice by the holder of the Series A Preferred Shares, stating the name and address of the assignee and identifying the securities of the Company as to which the rights in question are being assigned; and provided further, that any such assignee shall receive such assigned rights subject to all the terms and conditions of this Agreement.

5.2. Amendment of Rights. Any provision in this Agreement may be amended and the observance thereof may be waived (either generally or in a particular instance and either retroactively or prospectively), only by the written consent of (a) the Company; and (b) the persons or entities holding at least [***] percent ([***]%) of the Series A Preferred Shares then outstanding and their permitted assigns; provided, however, that (i) no provision hereof may be amended or waived, in each case, in any way which would adversely affect the rights of one holder of Series A Preferred Shares hereunder in a manner disproportionate to any adverse effect such amendment or waiver would have on other such holder without the consent of such disproportionately affected holder and (ii) any holder of Series A Preferred Shares may waive any of its rights hereunder without obtaining the consent of any other holders of Series A Preferred Shares or their assigns; provided, further, however, that Sections 1.1(a), 1.2(a), 7.1(m) and 9.5 of this Agreement shall not be amended or waived without the express written consent of Ascendis and Sections 1.1(a), 1.2(b), 7.1(m) and 9.5 of this Agreement shall not be amended or waived without the express written consent of Vivo Capital. Any amendment or waiver effected in accordance with this Section 5.2 shall be binding upon the Company, the holders of Series A Preferred Shares and their respective assigns. The Company shall give prompt written notice of any amendment, termination, or waiver hereunder to any party that did not consent in writing thereto.

6. CONFIDENTIALITY AND NON-DISCLOSURE.

6.1. Shareholder's Confidentiality Obligation. Each Investor agrees that such Investor will, and will cause its Affiliates and Representatives to, keep confidential and will not disclose, divulge, or use for any purpose (other than for its investment in the Company) the terms of this Agreement and any confidential information obtained from the Group Companies (including notice of the Company's intention to file a registration statement), unless such confidential information (a) is known or becomes known to the public in general (other than as a result of a breach of this Subsection by such Investor), (b) is or has been independently developed or conceived by such Investor without use of the Company's confidential information, or (c) is or has been made known or disclosed to such Investor by a third party without a breach of any obligation of confidentiality such third party may have to the Company; provided, however, that an Investor may disclose confidential information (i) to its Affiliates, attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company; (ii) to any prospective purchaser of any Registrable Securities from such Investor, if such prospective purchaser agrees to be bound by the provisions of this Subsection; (iii) to any existing or prospective Affiliate, partner, member, stockholder, or wholly owned subsidiary of such Investor in the ordinary course of business, provided that such Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information; or (iv) as may otherwise be required by law, regulation, rule, court order or subpoena (including the rules and regulations of the U.S. Securities and Exchange Commission), provided that such Investor promptly notifies the Company of such disclosure and takes reasonable steps to minimize the extent of any such required disclosure. For purposes of this Agreement, "**Affiliate**" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. For the avoidance of doubt, any breach of the confidentiality and non-use obligations by any of its Affiliates or Representative shall be deemed a breach by such Investor, for which such Investor shall be fully responsible.

6.2. Press Releases, Etc. No announcement regarding any of the Financing Terms in a press release, conference, advertisement, announcement, professional or trade publication, mass marketing materials or otherwise to the general public may be made without the Major Investors' prior written consent (which consent shall not be unreasonably withheld), except as may otherwise be required by law, regulation, rule, court order or subpoena (including the rules and regulations of the U.S. Securities and Exchange Commission). Following the execution of this Agreement, the Major Investors will issue an initial press release, the form and timing of which shall be agreed between the Major Investors.

6.3. Other Information. The provisions of this Section 6 shall be in addition to, and not in substitution for, the provisions of any separate nondisclosure agreement executed by any of the parties with respect to the transactions contemplated hereby.

6.4. Notices. All notices required under this section shall be made pursuant to Section 12.1 of this Agreement.

7. PROTECTIVE PROVISIONS.

7.1. Approval by Shareholders. In addition to such other limitations as may be provided in the Restated Articles, so long as at least twenty-five percent (25%) of the Series A Preferred Shares issued at the Initial Closing remain outstanding, none of the Group Companies shall, and the Founders shall procure that each of the Group Companies shall not, directly or indirectly, whether in a single transaction or series of related transactions, whether by amendment, merger, consolidation or otherwise, carry out any of the following actions except with the prior written approval of holders of more than [***] percent ([***]%) of the Series A Preferred Shares then outstanding, voting as a separate class:

(a) any repeal, amendment, modification or change of the memorandum or the articles or other similar constitutive documents of any Group Company;

(b) any amendment, modification or change of any rights, preferences, privileges or powers of, or any restrictions provided for the benefit of, the Series A Preferred Shares or any amendment, modification or change of any rights, powers or benefit attached to the Ordinary Shares or other classes or series of shares having the effect of or may result in any rights, preferences, privileges or powers of the Series A Preferred Shares being prejudiced;

(c) liquidation, dissolution, winding up or reorganization of any Group Company, or any Liquidation Event;

(d) any issue, allotment or grant of any options, warrants or similar rights conferring on any Person the right to acquire, any shares, securities or equity interest in the Group Companies (except where such issue, allotment or grant is incidental to the exercise of conversion rights applicable to the Series A Preferred Shares or pursuant to the pre-approved share option plans, share incentive scheme or other schemes and agreements of similar nature);

(e) any action that authorizes, creates or issues shares of any class or series, or other securities of whatever description, or reclassifies or converts any issued or outstanding shares of the Company into shares, having rights, priority or preferences superior to or on a parity with the Series A Preferred Shares, whether in terms of voting rights, dividends or amounts payable in the event of any voluntary or involuntary liquidation or distribution of the Company or otherwise;

(f) any increase or decrease in the number of authorized Series A Preferred Shares or Ordinary Shares;

(g) any repurchase or redemption of any shares or other securities of the Company other than repurchases of shares from former employees, officers, directors, consultants or other persons who performed services for the Company or any Group Company in connection with the cessation of such employment or service pursuant to the ESOP Plan (as defined below);

(h) the declaration or payment of a dividend on any share or other securities of any Group Company and any change of dividend policy of any Group Company;

(i) any action that creates, or authorizes the creation of, any debt security;

(j) changing the principal business of the Group Companies, entering into any new line of business, or exiting the current line of business;

(k) the creation, adoption and material amendment of any equity incentive plan or equivalent by the Group Companies (including total amount of options, exercise price and term of exercise);

(l) any increase or decrease in the authorized number of members of the board of directors of any Group Company;

(m) sell, assign, license, sublicense, pledge or encumber material technology or intellectual property to any third party; and

(n) any agreement or commitment by any Group Company to do any of the foregoing.

Notwithstanding anything to the contrary contained herein, where any act listed in clauses (a) through (n) above requires a resolution of the Members, and if the shareholders vote in favour of such act but the approval of the holders of more than [***] percent ([***]%) of the outstanding Series A Preferred Shares has not yet been obtained in accordance with this Section 7.1, the holders of Series A Preferred Shares that vote against such resolution shall have, in such vote at a meeting of the shareholders, the voting rights equal to the aggregate voting power of all the shareholders of the Company who voted in favour of the resolution plus one.

7.2. Approval by Board of Directors. In addition to such other limitations as may be provided in the Restated Articles, so long as the holders of Series A Preferred Shares are entitled to elect a Series A Director, none of the Group Companies shall, directly or indirectly, whether in a single transaction or series of related transactions, whether by amendment, merger, consolidation or otherwise, except with the prior written approval of each of the Series A Directors:

(a) make any loan or advance to, or own any share or other securities of, any subsidiary or other corporation, partnership, or other entity unless it is wholly owned by a Group Company;

(b) make any loan or advance to any person, including, any employee or director of any Group Company, except advances and similar expenditures in the ordinary course of business or under the terms of an equity incentive plan approved by the Board;

(c) guarantee any indebtedness except for trade accounts of the Group Companies or any subsidiary arising in the ordinary course of business;

(d) make any investment inconsistent with any investment policy approved by the Board;

(e) incur any aggregate indebtedness in excess of US$1,000,000 that is not already included in a Board-approved budget, other than trade credit incurred in the ordinary course of business;

(f) enter into or be a party to any transaction with any director, officer or employee of the Group Companies or any "associate" (as defined in Rule 12b-2 promulgated under the Exchange Act) of any such person, or with any shareholder or its affiliates or any director, officer or employee of such shareholder or its affiliates or any "associate" of any such person, other than transactions made in the ordinary course of business and pursuant to reasonable requirements of the Group Companies' business and upon fair and reasonable terms that are approved by a majority of the Board;

(g) hire, fire, or change the compensation of the executive officers, and approve any and all option grants to the executive officers of any Group Company;

(h) sell, assign, license, sublicense, pledge or encumber material technology or intellectual property of any Group Company;

(i) enter into any corporate strategic relationship involving the payment, contribution or assignment by any Group Company or to any Group Company of assets greater than US$500,000; or

(j) any agreement or commitment by any Group Company to do any of the foregoing.

7.3. Termination. The provisions set forth under this Section 7 shall terminate upon the earlier to occur of (i) the closing of a Liquidation Event; and (ii) immediately prior to the consummation of the Qualified Initial Public Offering.

8. DRAG ALONG

8.1. In the event that (i) the holders of at least [***] percent ([***]%) of the outstanding Ordinary Shares (on an as-converted basis) (the "**Approving Shareholders**"); and (ii) the Board of Directors approve in writing, to sell or transfer the shares or assets of any Group Company in any transaction or a series of related transactions that would qualify as a Liquidation Event, to a bona fide third party, or a group of bona fide related parties (the "**Change of Control**"), then the Company shall promptly notify each of the remaining shareholders of the Company (the "**Remaining Shareholders**", including without limitation, each of the holders of Ordinary Shares and Series A Preferred Shares) in writing of such vote, consent and/or agreement and the material terms and conditions of such Change of Control, whereupon each Remaining Shareholder shall, in accordance with instructions received from the Company (the "**Drag Along Instructions**"), vote all of its voting securities of the Company in favor of, otherwise consent in writing to, and/or otherwise sell or transfer all of their shares in such Change of Control (including without limitation tendering original share certificates for transfer, signing and delivering share transfer certificates, share sale or exchange agreements, and certificates of indemnity relating to any shares in the share capital of the Company in the event that such Remaining Shareholder has lost or misplaced the relevant share certificate) on the same terms and conditions as were agreed to by the Approving Shareholders.

8.2. Notwithstanding the foregoing, a Remaining Shareholder will not be required to comply with Section 8.1 above in connection with any proposed Change of Control, unless the liability for indemnification, if any, of such Remaining Shareholder in the Change of Control and for the inaccuracy of any representations and warranties made by the Company and/or its shareholders in connection with such Change of Control, is several and not joint with any other Person, and is proportionate to, and does not exceed, the amount of consideration paid to such Remaining Shareholder in connection with such Change of Control.

8.3. In furtherance of the foregoing, the Company is hereby expressly authorized by each Remaining Shareholder to take any or all of the following actions on such Remaining Shareholder's behalf (without receipt of any further consent by such Remaining Shareholder), provided such Remaining Shareholder fails to take necessary actions as required under the Drag Along Instructions, to: (i) vote all of the voting securities of such Remaining Shareholder in favor of any such Change of Control and cause the director(s) appointed by such Remaining Shareholder to vote in favor of any such Change of Control; (ii) otherwise consent on such Remaining Shareholder's behalf to such Change of Control; (iii) sell all of such Remaining Shareholder's shares in such Change of Control, in accordance with the terms and conditions of this Section; and/or (iv) act as the Remaining Shareholder's attorney in fact in relation to any such Change of Control and have the full authority to sign and deliver, on behalf of such Remaining Shareholder, share transfer certificates, share sale or exchange agreements and certificates of indemnity relating to any shares in the share capital of the Company in the event that such Remaining Shareholder has lost or misplaced the relevant share certificate. Notwithstanding anything to the contrary in the Shareholders Agreement, none of the transfer restrictions set forth in the Shareholders Agreement shall apply in connection with such Change of Control.

8.4. Upon written notice to the Company from the Approving Shareholders, the Company shall initiate a process intended to result in a Change of Control and shall cause its officers, employees, consultants, counsel and advisors to take all necessary and appropriate actions to facilitate a Change of Control.

9. COVENANTS; UNDERTAKINGS

9.1. Controlled Foreign Corporation. Each year, based on and in reliance of the information provided by the shareholders of the Company (the "**Shareholders**") within a reasonable time after being requested, the Company shall make due inquiry with its tax advisors regarding whether the Company or any of its Subsidiaries is treated as a "Controlled Foreign Corporation" ("**CFC**") as defined in the United States Internal Revenue Code of 1986 (the "**Code**"), whether any portion of the Company's or any of its Subsidiaries' income is (a) "Subpart F Income" (as defined in Section 952 of the Code) ("**Subpart F Income**") or (b) "global intangible low-taxed income" (as defined in Section 951A(b) of the Code) ("**GILTI**") and each Shareholder's share, if any, of such Subpart F Income and/or GILTI (regardless of whether a Shareholder is a "United States Shareholder" or not). Upon written request of any Investor who is a United States Shareholder (or whose direct or indirect owners are United States Shareholders) with respect to the Company or any Group Company within the meaning of Section 951(b) of the Code, the Company will (i) use best efforts to provide in writing such information as is in its possession and reasonably available concerning its shareholders and affiliates to assist such Investor in determining whether the Company or any Group Company is a CFC and (ii) provide such Investor with reasonable access to such information as is in the Company's or Group Company's possession and reasonably available as may be required by such Investor (A) to determine the Company's (or Group Company's) status as a CFC, (B) to determine whether such Investor is required to report its pro rata portion of the Company's (or Group Company's) "**Subpart F income**" (as defined in Section 952 of the Code) on its United States federal income tax return, or (C) to allow such Investor to otherwise comply with applicable United States federal income tax laws (including with respect to the making of any determinations under Section 951A of the Code); provided that the Company may require such Investor to enter into a confidentiality agreement in customary form.

9.2. Passive Foreign Investment Company. The Company shall use commercially reasonable efforts to avoid being a "passive foreign investment company" within the meaning of Section 1297 of the Code ("**PFIC**") for the current and any future taxable year. The Company shall make due inquiry with its tax advisors on at least an annual basis regarding its status as a PFIC, and if the Company is informed by its tax advisors that it has become a PFIC, or that it is likely that the Company will be classified as a PFIC for any taxable year, the Company shall promptly notify each Investor of such status or risk, as the case may be, in each case no later than forty-five (45) days following the end of the Company's taxable year. The Company shall provide its Investors with annual financial information in the form to the reasonable satisfaction of such Investor as soon as reasonably practicable following the end of each taxable year of such Investor (but in no event later than forty-five (45) days following the end of each such taxable year), and shall, upon the request in writing by any Investor, provide such Investor with access to such other information, as is in the Company's possession and reasonably available, as may be required for purposes of filing U.S. federal income tax returns in connection with a qualified electing fund election or other tax filing in respect of the Company's status of a PFIC. In the event that it is determined by the Company's or such Investor's tax advisors that the control documents in place between one or more of the Company's wholly owned Subsidiaries and/or the Company, on the one hand, and any of the Group Companies organized in the PRC that is not a wholly foreign owned enterprise, on the other hand, do not allow the Company to look through the Group Companies to their assets and income for purposes of the PFIC rules and regulations under the Code, the Company shall use its best efforts to take such actions as are reasonably necessary or advisable, including the amendment of such control documents, to qualify for such look-through treatment of the Group Companies under the PFIC rules and regulations under the Code.

9.3. Subsidiary Covenants. The Company shall at any time institute and shall keep in place arrangements satisfactory to the Board such that the Company (i) will control the operations of any Group Company and (ii) will be permitted to properly consolidate the financial results for such entity in consolidated financial statements for the Company prepared under the PRC GAAP and IFRS. The Company shall, and shall cause each Group Company and use its reasonably best efforts to cause such Group Company's respective directors, officers, employees, agents and other persons acting on its behalf or purporting to act on its behalf to, comply with the US Foreign Corrupt Practices Act, as amended, in all material respects.

9.4. Additional Subsidiary Covenants. The Company shall take all necessary actions to maintain its Subsidiaries, as is necessary to conduct the Company's business as conducted or as proposed to be conducted. The Company shall use its best efforts to cause each Subsidiary to comply in all material respects with all applicable laws, rules, and regulations. All material aspects of such formation, maintenance and compliance of each Subsidiary shall be subject to the review, approval and oversight by the Board.

9.5. Non-Compete. Ascendis undertakes and covenants to the Company that commencing from the date of this Agreement, it will not, without the prior written consent of the Company, either on its own account or through any of his/its Controlled Affiliates, or in conjunction with or on behalf of any other person: (i) carry out or be engaged in the research, development, manufacture or commercialization of [***] in the People's Republic of China (including Hong Kong, Macao and Taiwan) (the "**Competing Business**"); (ii) directly or indirectly own any interest in a third party engaged in the Competing Business other than holding in aggregate not more than [***] percent ([***]%) of the issued share capital of any entity engaged in the Competing Business as a passive investor; (iii) solicit or entice away or attempt to solicit or entice away from any Group Company, any person, firm, company or organization who is a customer, client, employee, representative, agent or correspondent of such Group Company or in the habit of dealing with such Group Company, or (iv) provide services to any entity engaged in the Competing Business [***]. For clarity; subsection (iv) shall not apply to services that Ascendis provides to a competing company outside the Territory for the use outside of the Territory. For avoidance of the doubt, all activities performed pursuant to the following agreements shall not constitute engagement in the Competing Business and neither Ascendis nor its Controlled Affiliates shall be deemed to have engaged in any Competing Business as a result of any activities performed under such agreements: (a) [***] and (b) [***]. In the event that any entity, in which Ascendis owns directly or indirectly more than [***] percent ([***]%) of the issued share capital and/or Ascendis is not merely a passive investor, becomes [***] in the Competing Business, Ascendis shall decrease its holding in such entity to [***] percent ([***]%) [***] and in any event within [***] ([***]) months after the time when Ascendis comes to own directly or indirectly more than [***] percent ([***]%) of the issued share capital of such entity engaged in the Competing Business [***]. The provisions of this Section 9.5 shall terminate upon the earlier to occur of (i) the closing of a Liquidation Event; or (ii) the termination of each of the Exclusive License Agreements dated the date hereof by and among the Company and Ascendis Pharma Growth Disorders A/S, Ascendis Pharma Endocrinology Division A/S and Ascendis Pharma Bone Diseases A/S (the "**Rights Agreements**"). For clarity, nothing in this Section 9.5 shall restrict or limit the ability of Ascendis or its Affiliates to fulfill or perform its obligations under any other agreement with the Company, including without limitation any Rights Agreement or any clinical or commercial supply agreement entered into by Ascendis or its Affiliates with the Company. [***].

9.6. Compliance. The Group Companies shall conduct their respective business as currently conducted or proposed to be conducted in compliance with all applicable Laws of each relevant jurisdiction on a continuing basis.

9.7. Management. Vivo Capital shall be entitled to nominate the candidates for the Chief Executive Officer and the Chief Business Officer of the Company to be approved by the Board. Effective as of the Initial Closing, Ms. Daisy XU and Dr. Dandan DONG shall serve as the founding Chief Executive Officer and Chief Business Officer of the Company to work through tax related matters in the PRC, recruit CEO and key management team members of the Group Companies, design regulatory strategy, and perform other functions as approved by the Board. The Company shall reasonably compensate for the services provided by Ms. Daisy XU and Dr. Dandan DONG to the Group Companies. The provisions of this Section 9.7 shall terminate upon the earlier to occur of (i) the closing of a Liquidation Event; and (ii) immediately prior to the consummation of the Qualified Initial Public Offering.

9.8. ESOP. As soon as practicable after the Initial Closing, the Company shall cause an employee equity incentive plan (the "**ESOP Plan**") to be duly adopted by the Board and shareholders of the Company, pursuant to which [***] Ordinary Shares (representing [***]% of the total number of Ordinary Shares of the Company immediately after the Initial Closing on a fully diluted and as-converted basis) shall be reserved for future issuance to officers, directors, employees, consultants or service providers of the Group Companies. The Company shall cause each of the grantees under the ESOP Plan to enter into such grant documents which shall provide the Company with a right of first refusal on grantee's transfer of shares and shall further provide that if the Company fails to exercise its right of first refusal, each of the Investors shall have a right of first refusal with respect to the shares not purchased by the Company, in accordance with its pro rata ownership of the Company (on an as-converted basis), and if any Investor fails to exercise its right of first refusal with respect to such shares, it shall have the right to sell its pro rata shares together with the transferring grantee. In addition, the Company shall ensure that each holder of the Ordinary Shares representing no less than one percent (1%) of the Company's total outstanding Ordinary Shares on fully-diluted and as-converted basis shall execute a joinder agreeing to the terms of this Agreement.

9.9. D&O Insurance. The Company will purchase D&O insurance with a carrier and in an amount satisfactory to the Board within 60 days of the Initial Closing. In the event any Group Company merges with another entity and is not the surviving corporation, or transfers all of its assets, proper provisions shall be made so that successors of such Group Company assume such Group Company's obligations with respect to indemnification of Directors. Upon request by either of the Major Investors, the other Group Companies will purchase D&O insurance with a carrier and in an amount satisfactory to the board of directors of the relevant Group Company.

9.10. Maintaining and Obtaining Licenses and Permits for the Principal Business. As soon as practicable after the Initial Closing, each of the Group Companies shall (i) maintain in a timely manner all requisite Consents and Permits for conducting the Principal Business in compliance with all material aspects with applicable Laws, and (ii) if so required by any applicable Laws, obtain additional Consents and Permits necessary for conducting the Principal Business as soon as possible but in any event no later than the time limit required by the applicable Laws or the competent Governmental Authorities.

9.11. Employment Agreement and Confidentiality, Non-Competition and Intellectual Property Rights Agreements. The Group Companies shall cause each of their respective current and future employees to enter into an employment agreement in form and substance satisfactory to the Major Investors. The Group Companies shall cause each of their respective current and future employees and consultants to enter into a confidentiality, non-competition and proprietary information and inventions assignment agreement in form and substance satisfactory to the Major Investors.

9.12. Compliance & Anti-Corruption. Upholding ethical standards, acting with integrity and in compliance with applicable laws and regulations, is essential to the Group Companies. The Group Companies undertakes to conduct its business in accordance with all applicable laws and regulations. The Company shall not (and shall not permit any of its Subsidiaries or Affiliates or any of its or their respective directors, officers, managers, employees, independent contractors, representatives or agents to) promise, authorize or make any payment to, or otherwise contribute any item of value to, directly or indirectly, to any third party, including any Non-U.S. Official (as (as such term is defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "**FCPA**")), in each case, in violation of the FCPA, the U.K. Bribery Act, or any other applicable anti-bribery or anti-corruption law. The Company shall (and shall cause each of its subsidiaries and affiliates to) maintain processes and procedures designed to prevent any person working for or engaged by the Company and its subsidiaries and affiliates or any other third party in any way connected to the Company, from

engaging in any activity, practice or conduct which would infringe any anti-bribery and anti-corruption laws, regulations and codes, including but not limited to the UK Bribery Act and the FCPA. Furthermore, the Company shall (and shall cause each of its subsidiaries and affiliates to) maintain systems of internal controls (including, but not limited to, accounting systems, purchasing systems and billing systems) to ensure compliance with the FCPA, the U.K. Bribery Act, or any other applicable anti-bribery or anti-corruption law. Upon request, the Company agrees to provide responsive information, documentation and/or certifications concerning its (and each of its Subsidiaries and Controlled Affiliates) compliance with applicable anti-corruption laws. The Company shall promptly notify each Investor in writing if the Company suspects or becomes aware of any actual or potential fraud, non-compliance, misconduct or enforcement action, and promptly take all appropriate steps to resolve and correct any identified non-conformity. The Company undertakes to maintain adequate and accurate books and records to ensure compliance, including but not limited to using practices and normal systems and methodologies according to IFRS. The Company shall, and shall cause any direct or indirect subsidiary or entity controlled by it, whether now in existence or formed in the future, to comply with the FCPA and any other applicable anti-corruption law. The Company shall use its best efforts to cause any direct or indirect subsidiary, whether now in existence or formed in the future, to comply in all material respects with all applicable laws.

10. Termination and Consequences of Termination.

10.1. Termination.

(a) This Agreement (i) may be terminated at any time by written agreement between each of the Major Investors; and (ii) shall be automatically terminated upon the dissolution of the Company.

(b) In addition, upon the occurrence of any of the events listed in Section 10.1 (each, a "**Termination Event**"), the holders of [***] percent ([***]%) of the Series A Preferred Shares (excluding the Series A Preferred Shares held by the Party in breach or subject to the Termination Event) (the "**Terminating Party**") shall be entitled to terminate this Agreement, with immediate effect, by issuing a written notice to the other shareholders of the Company (the "**Non-Terminating Party**"), with a copy to the Company, specifying the applicable Termination Event:

(i) if there is a material breach of Section 9.5 under this Agreement by the Non-Terminating Party;

(ii) if any Major Investor files any petition or action for relief under any bankruptcy, reorganization, insolvency or moratorium law or any other law for the relief of, or relating to, debtors, now or hereafter in effect, or makes any assignment for the benefit of creditors or takes any corporate action in furtherance of any of the foregoing;

(iii) if an involuntary petition is filed against any Major Investor (unless such petition is dismissed or discharged within 60 days under any bankruptcy statute now or hereafter in effect), or a custodian, receiver, trustee, assignee for the benefit of creditors (or other similar official) is appointed to take possession, custody or control of any property of such Major Investor; or

(iv) if the Rights Agreements were wrongfully terminated by the Non-Terminating Party or terminated due to the Non-Terminating Party's breach or failure to fulfill its obligations under the Rights Agreements.

10.2. Effect of Termination. Upon the termination of this Agreement, the Company shall be dissolved and liquidated in accordance with the Restated Articles, the relevant Cayman Island Laws. The Shareholders shall take any and all lawful actions, including without limitation exercising their respective voting rights and causing their directors to exercise their voting rights in the Board, to ensure the approval of the dissolution of the Company. Notwithstanding anything to the contrary, the provisions of Sections 6, 10, 11 and 12 shall survive the expiration or early termination of this Agreement and the termination, dissolution or liquidation of the Company.

11. INDEMNIFICATION.

11.1. General Indemnity.

(a) If a Party fails to perform any of its obligations under this Agreement (the "**Breaching Party**"), then, following written notice by any other parties hereto (the "**Non-Breaching Party**") and a ten (10) day opportunity to cure such breach (should it be capable of cure), the Breaching Party shall indemnify such Non-Breaching Party and the Company for, all claims, losses, damages, liabilities, documented costs and expenses (including reasonable attorneys' fees) (the "**Losses**") which have been incurred by such Non-Breaching Party or the Company in respect of a breach by a Breaching Party of any of its representations and warranties, covenants, undertakings, or other obligations under this Agreement.

(b) NO PARTY SHALL BE LIABLE TO OTHER PARTIES, ITS RELATED PARTIES, THEIR RESPECTIVE OFFICERS, DIRECTORS, AGENTS, REPRESENTATIVES OR EMPLOYEES WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT (OTHER THAN BREACH OF THE CONFIDENTIALITY OR NON-COMPETITION OBLIGATIONS HEREUNDER) UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOST PROFITS EXCEPT FOR LOSSES ACTUALLY INCURRED IN THIRD PARTY CLAIM(S).

11.2. Claim Notice Procedure.

Without limiting any other rights of the Non-Breaching Party in any way (including their rights to pursue damages in respect of a claim for breach of any covenant or other obligation), any Non-Breaching Party shall have the right to make a claim for indemnity under this Agreement at any time after the date hereof by issuing a written claim notice (the "**Claim Notice**") to the Breaching Party. The Claim Notice shall describe the breach in question along with the Party's determination of the following:

(a) the amount which would be necessary to put the Company and/or the Non-Breaching Party, as the case may be, into the financial position which would have existed had there been no breach of any representations and warranties, covenants, undertakings, or other obligations in question; and

(b) all costs suffered or incurred by the Non-Breaching Party directly or indirectly, as a result of or in connection with such breach of representations and warranties, covenants, undertakings, or other obligations.

11.3. Payment under Claim Notice.

Within fifteen (15) Business Days after receipt of a Claim Notice, the Breaching Party shall pay to the Company and/or the Non-Breaching Party all of the amounts specified in the Claim Notice.

11.4. No Deduction.

All sums payable by the Breaching Party to the Company or the Non-Breaching Party under Section 11 shall be paid free and clear of all deductions or withholdings whatsoever save only as may be required by law. If any such deductions or withholdings are required by law, the Breaching Party shall be obliged to pay to the relevant person such sum as will, after deduction or withholding has been made, leave that person with the same amount as it would have been entitled to receive in the absence of any requirement to make a deduction or withholding.

11.5. Director Indemnification.

To the fullest extent permitted by applicable laws, the Company shall indemnify and hold harmless any Director for any damage, demand, claim, liability, obligation, loss, cost, expense (including, without limitation, the fees and disbursements of attorneys, accountants, and consultants), deficiency, interest, penalty, impositions, assessments or fines of any kind or nature, whether known or unknown, fixed or contingent, arising out of or resulting from such Director's service on the Board or any committee thereof.

12. GENERAL PROVISIONS.

12.1. Notices. Except as may be otherwise provided herein, all notices, requests, waivers and other communications made pursuant to this Agreement shall be in writing and shall be conclusively deemed to have been duly given (a) when hand delivered to the other party, upon delivery; (b) when sent by facsimile at the number set forth in Exhibit A hereto, upon receipt of confirmation of error-free transmission; (c) seven (7) Business Days after deposit in the mail as air mail or certified mail, receipt requested, postage prepaid and addressed to the other party as set forth in Exhibit A; (d) four (4) Business Days after deposit with an international overnight delivery service, postage prepaid, addressed to the parties as set forth in Exhibit A with next-business day delivery guaranteed, provided that the sending party receives a confirmation of delivery from the delivery service provider; or (e) when sent by email at the email address set forth in Exhibit A hereto, upon receipt of confirmation of receipt. Each person making a communication hereunder by facsimile shall promptly confirm by telephone to the person to whom such communication was addressed each communication made by it by facsimile pursuant hereto but the absence of such confirmation shall not affect the validity of any such communication. A party may change or supplement the addresses given above, or designate additional addresses, for purposes of this Section 12.1 by giving the other party written notice of the new address in the manner set forth above.

12.2. Entire Agreement. This Agreement and the Share Purchase Agreement, any other Transaction Documents, together with all the exhibits hereto and thereto, constitute and contain the entire agreement and understanding of the parties with respect to the subject matter hereof and supersedes any and all prior negotiations, correspondence, agreements, understandings, duties or obligations between the parties respecting the subject matter hereof. Capitalized terms which are not defined hereinto shall have the same meaning as such in the Share Purchase Agreement.

12.3. Governing Law. This Agreement shall be governed by and construed exclusively in accordance with the laws of the Hong Kong Special Administrative Region without regard to principles of conflicts of law thereunder.

12.4. Severability. If any provision of this Agreement is found to be invalid or unenforceable, then such provision shall be construed, to the extent feasible, so as to render the provision enforceable and to provide for the consummation of the transactions contemplated hereby on substantially the same terms as originally set forth herein, and if no feasible interpretation would save such provision, it shall be severed from the remainder of this Agreement, which shall remain in full force and effect unless the severed provision is essential to the rights or benefits intended by the parties. In such event, the parties shall use best efforts to negotiate, in good faith, a substitute, valid and enforceable provision or agreement which most nearly effects the parties' intent in entering into this Agreement.

12.5. Third Parties. Nothing in this Agreement, express or implied, is intended to confer upon any person, other than the parties hereto and their permitted successors and assigns any rights or remedies under or by reason of this Agreement.

12.6. Successors and Assigns. Subject to the provisions of Section 5.1, the provisions of this Agreement shall inure to the benefit of, and shall be binding upon, the successors, permitted assigns, heirs, executors and administrators of the Parties hereto whose rights or obligations hereunder are affected by such provisions. Notwithstanding anything contrary in this Agreement, this Agreement and the rights and obligations herein may be assigned or transferred by any Investors to any of its Affiliates; provided that in each case the transferee will agree by executing a Deed of Adherence in the form attached hereto as Exhibit B to be subject to the terms of this Agreement to the same extent as if it were an original Investor hereunder. "**Person**" shall mean any individual, corporation, partnership, limited partnership, proprietorship, association, limited liability company, firm, trust, estate or other enterprise or entity. "**Control**" shall mean the power or authority, whether exercised or not, to direct the business, management and policies of a Person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise; provided, that such power or authority shall conclusively be presumed to exist upon possession of beneficial ownership or power to direct the vote of more than fifty percent (50%) of the votes entitled to be cast at a meeting of the members or shareholders of such Person or power to control the composition of a majority of the board of directors of such Person. The terms "**Controlled**" and "**Controlling**" have meanings correlative to the foregoing. Notwithstanding anything to the contrary contained herein, no Investor shall be deemed to be an Affiliate (or Controlled Affiliate) of any Group Company and the Group Companies shall not be deemed to be an Affiliate (or Controlled Affiliate) of any Investor.

12.7. Interpretation; Captions. This Agreement shall be construed according to its fair language. The rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not be employed in interpreting this Agreement. The captions to sections of this Agreement have been inserted for identification and reference purposes only and shall not be used to construe or interpret this Agreement. Unless otherwise expressly provided herein, all references to Sections and Exhibits herein are to Sections and Exhibits of this Agreement.

12.8. Counterparts. This Agreement may be executed in one or more counterparts and may be delivered by electronic or facsimile transmission, all of which shall be considered one and the same agreement and each of which shall be deemed an original.

12.9. Adjustments for Share Splits, Etc. Wherever in this Agreement there is a reference to a specific number of shares of Series A Preferred Shares or Ordinary Shares of the Company, then, upon the occurrence of any subdivision, combination or share dividend of the Series A Preferred Shares or Ordinary Shares, the specific number of shares so referenced in this Agreement shall automatically be proportionally adjusted to reflect the effect on the outstanding shares of such class or series of shares by such subdivision, combination or share dividend.

12.10. Aggregation of Shares. All Series A Preferred Shares or Ordinary Shares held or acquired by Affiliated entities or persons (as defined in Rule 144 under the Securities Act) shall be aggregated together for the purpose of determining the availability of any rights under this Agreement.

12.11. Shareholders Agreement to Control. If and to the extent that there are inconsistencies between the provisions of this Agreement and those of the Restated Articles, the terms of this Agreement shall prevail between the parties to this Agreement other than the Company. The parties other than the Company agree to take all actions necessary or advisable, as promptly as practicable after the discovery of such inconsistency, to amend the Restated Articles so as to eliminate such inconsistency.

12.12. Dispute Resolution.

(a) Negotiation between Parties. The Parties agree to negotiate in good faith to resolve any dispute, controversy, difference or claim arising out of or relating to this Agreement, including the existence, validity, interpretation, performance, breach or termination thereof between them regarding this Agreement. If the negotiations do not resolve the dispute to the reasonable satisfaction of all Parties in dispute within thirty (30) days after one party delivers notice of dispute to the others, Section 12.12(b) shall apply.

(b) Arbitration. In the event the Parties in dispute are unable to settle a dispute between them regarding this Agreement in accordance with subsection (i) above, such dispute shall be referred to and finally resolved by arbitration at the Hong Kong International Arbitration Centre (the "**HKIAC**") for arbitration in Hong Kong. The arbitration shall be conducted in accordance with the HKIAC Administered Arbitration Rules in force at the time of the initiation of the arbitration, which rules are deemed to be incorporated by reference into this subsection (ii). There shall be three (3) arbitrators. Each Party or group of Parties in dispute shall be entitled to nominate one (1) arbitrator with the third arbitrator jointly nominated by the disputing Parties within thirty (30) days after the initiation of the arbitration. Each of the arbitrators so nominated shall be qualified to practice the laws of Hong Kong. In the event that the disputing Parties cannot jointly agree on the third arbitrator within such thirty (30) day period, the HKIAC shall appoint such arbitrator. The arbitral proceedings shall be conducted in English. The award of the arbitral tribunal shall be final and binding upon the Parties thereto.

12.13. Further Actions. Each Shareholder of the Company agrees that it shall use its best effort to enhance and increase the value and principal business of the Group Companies.

12.14. Waiver. The Company acknowledges that the Investors will likely have, from time to time, information that may be of interest to the Company or its Subsidiaries ("**Information**") regarding a wide variety of matters including (i) the technologies, plans and services, and plans and strategies relating thereto of such Investor, (ii) current and future investments such Investor has made, may make, may consider or may become aware of with respect to other companies and other technologies, products and services, including technologies, products and services that may be competitive with those of the Company or any of its Subsidiaries, and (iii) developments with respect to the technologies, products and services, and plans and strategies relating thereto, of other companies, including companies that may be competitive with the Company or any of its Subsidiaries. The Company recognizes that a portion of such Information may be of interest to the Company or any of its Subsidiaries. Such Information may or may not be known by the Investors or the Series A Directors. The Company, as a material part of the consideration for this Agreement, agrees that the Investors or the Series A Directors shall not have any duty to disclose any Information to the Company or any of its Subsidiaries, or permit the Company or any of its Subsidiaries to participate in any projects or investments based on any such Information, or otherwise to take advantage of any opportunity that may be of interest to the Company or any of its Subsidiaries if it were aware of such Information, and hereby waives, to the extent permitted by law, any claim based on the corporate opportunity doctrine or otherwise that could limit the Investor's ability to pursue opportunities based on such Information or that would require the Investors, the Series A Directors or their representative(s), to disclose any such Information to the Company or any of its Subsidiaries or offer any opportunity relating thereto to the Company or any of its Subsidiaries.

12.15. Additional Investors. Notwithstanding anything to the contrary contained herein, if the Company issues additional Series A Preferred Shares after the date hereof pursuant to the Share Purchase Agreement, as such agreement may be amended from time to time in accordance with its terms, any purchaser of such Series A Preferred Shares may become a party to this Agreement by executing and delivering to the Company an additional counterpart signature page to this Agreement and thereafter shall be deemed an "**Investor**" for all purposes hereunder.

— REMAINDER OF THIS PAGE LEFT INTENTIONALLY BLANK —

IN WITNESS WHEREOF, the parties have caused their respective duly authorized representatives to execute this Agreement as of the date and year first above written.

COMPANY:

VISEN Pharmaceuticals

By: /s/ Shan Fu
Name: Shan Fu
Title: Director

SIGNATURE PAGE OF SHAREHOLDERS AGREEMENT

IN WITNESS WHEREOF, the parties have caused their respective duly authorized representatives to execute this Agreement as of the date and year first above written.

INVESTORS:

ASCENDIS PHARMA A/S

By: /s/ Michael Wolff Jensen, /s/ Jan Mikkelsen
Name: Michael Wolff Jensen/Jan Mikkelsen
Title: Chairman/CEO
Address: Tuborg Boulevard 12, DK-2900, Hellerup

ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S

By: /s/ Michael Wolff Jensen, /s/ Jan Mikkelsen
Name: Michael Wolff Jensen/Jan Mikkelsen
Title: Chairman/CEO
Address: Tuborg Boulevard 12, DK-2900, Hellerup

ASCENDIS PHARMA BONE DISEASES A/S

By: /s/ Michael Wolff Jensen, /s/ Jan Mikkelsen
Name: Michael Wolff Jensen/Jan Mikkelsen
Title: Chairman/CEO
Address: Tuborg Boulevard 12, DK-2900, Hellerup

ASCENDIS PHARMA GROWTH DISORDERS A/S

By: /s/ Michael Wolff Jensen, /s/ Jan Mikkelsen
Name: Michael Wolff Jensen/Jan Mikkelsen
Title: Chairman/CEO
Address: Tuborg Boulevard 12, DK-2900, Hellerup

IN WITNESS WHEREOF, the parties have caused their respective duly authorized representatives to execute this Agreement as of the date and year first above written.

INVESTORS:

VIVO PLENILUNE IX LIMITED

By: /s/ Albert Cha
Name: Albert Cha
Title: Director
Address: 505 Hamilton Avenue, Suite 207, Palo Alto, CA 94301

IN WITNESS WHEREOF, the parties have caused their respective duly authorized representatives to execute this Agreement as of the date and year first above written.

Sofinnova Venture Partners IX, L.P.

By: Sofinnova Management IX, L.L.C.
its General Partner

By /s/ James Healy
James Healy, Managing Member

SIGNATURE PAGE OF SHAREHOLDERS AGREEMENT

EXHIBIT A
PARTIES

Part I Investors

Name of Investors	**Number of Series A Preferred Shares**
Ascendis Pharma Endocrinology Division A/S	[***]
Ascendis Pharma Bone Diseases A/S	[***]
Ascendis Pharma Growth Disorders A/S (together with Ascendis Pharma Endocrinology Division A/S and Ascendis Pharma Bone Diseases A/S, "**Ascendis**")	[***]
Vivo Plenilune IX Limited ("**Vivo Capital**")	[***]
Sofinnova Venture Partners IV, L.P. ("**Sofinnova**")	[***]
Total	[***]

Part III Notice Address

For the purpose of the notice provisions contained in this Agreement, the following are the initial addresses of each Party:

If to the Company:

Address: International Corporation Services Ltd., P.O. Box 472, Harbour Place, 2nd Floor, 103 South Church Street, George Town, Grand Cayman KY1-1106, Cayman Islands

With a copy to:

Vivo Capital

Address: 505 Hamilton Avenue, Suite 207, Palo Alto, CA 94301
Tel: (650) 688-0818
Attention: Albert Cha
E-mail address: acha@vivocapital.com

and

Ascendis

Address: Tuborg Boulevard 12
2900 Hellerup
Denmark
Tel: +45 70 22 22 44
Attention: Michael Wolff Jensen
E-mail address: mwj@ascendispharma.com

If to Ascendis

Tuborg Boulevard 12
2900 Hellerup
Denmark
Attention: Michael Wolff Jensen
E-mail address: mwj@ascendispharma.com

If to Vivo Capital

Tel: (650) 688-0818
Attention: Albert Cha
E-mail address: acha@vivocapital.com

If to Sofinnova

3000 Sand Hill Road, Bldg. 4, Suite 250
Menlo Park, CA 94025

EXHIBIT A

EXHIBIT B

FORM OF DEED OF ADHERENCE

To: VISEN Pharmaceuticals
Parties to the Shareholders Agreement (as defined below)

From: _____

Date: _____

Dear Sirs,

Deed of Adherence

The undersigned hereby agree and covenant with each of you pursuant to this Deed of Adherence that the undersigned will abide by all the provisions of the Shareholders Agreement entered into by and among the Company and each of the parties named therein, dated as of [DATE], 2018, as amended from time to time (the "**Shareholders Agreement**"), as the Investors under the terms of the Shareholders Agreement and a party to the Shareholders Agreement.

[_____]

By: _____
Name:
Title:

Address:

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

EXECUTION VERSION
CONFIDENTIAL

Exclusive Licence Agreement

between

Ascendis Pharma Growth Disorders A/S

as the Licensor or Ascendis on the one hand

and

VISEN PHARMACEUTICALS

as the Licensee on the other hand

CONTENTS

THIS EXCLUSIVE LICENCE AGREEMENT (the "Agreement") is dated November 7, 2018 and made

BETWEEN:

(1) **ASCENDIS PHARMA GROWTH DISORDERS A/S**, ("Licensor" or "Ascendis"), a company registered in Denmark with its registered office at Tuborg Boulevard 5, DK-2900 Hellerup, Denmark;

(2) **VISEN PHARMACEUTICALS**, ("Licensee"), a company established under the laws of the Cayman Islands with its registered address at P.O. Box 472, 2nd Floor, Harbour Place, 103 South Church Street, George Town, Grand Cayman KY1-1106, Cayman Islands.

Ascendis and the Licensee are each a "Party", and together the "Parties", to this Agreement.

Background:

(A) Ascendis and its Affiliates Control proprietary rights, titles and interests in patents and technical information relating to Licensed Products (as defined below) within the area of growth disorders.

(B) The Licensee wishes to develop and to commercialise such Licensed Products in the Field in the Territory (such terms defined below), and Ascendis wishes to grant the Licensee an exclusive licence under certain patents, technical information and other intellectual property to develop and commercialise such Licensed Products in the Field in the Territory, on the terms and conditions of this Agreement.

THE PARTIES AGREE THAT:

1. **Interpretation**

1.1 **Definitions**

"Accounting Standard" means, with respect to the Licensee, either: (a) International Financial Reporting Standards ("IFRS"); or (b) United States generally accepted accounting principles ("GAAP"), in either case, which standards or principles (as applicable) are currently used at the applicable time, and as consistently applied, by the Licensee.

"Affiliate" means any business Entity which from time-to-time controls, is controlled by or is under common control with a Party to this Agreement, in each case only for so long as such control exists. As used in this definition, "control" of an Entity means the beneficial ownership (either directly or indirectly) of more than fifty percent (50%) of the total voting power of the shares or securities then outstanding normally entitled to vote in elections of the board of directors or other managing authority of such Entity. For the avoidance of doubt, neither Licensee nor any of its subsidiaries shall be considered as an Affiliate of Ascendis and an Affiliate of Ascendis shall not be considered as an Affiliate of either Licensee or its subsidiaries for the purposes of this Agreement.

"Applicable Laws" means all laws, statutes, codes, ordinances, rules and regulations that have been enacted (including without limitation by a Regulatory Authority) in any jurisdiction in the Territory and which are in force as of the Effective Date or come into force during the term of this Agreement and that are applicable to the research, development, Manufacture, or commercialization of Licensed Product or the activities of the Parties under this Agreement, including, without limitation: (a) applicable regulations and guidelines of the NMPA and other Regulatory Authorities and the ICH guidelines; (b) applicable Good Clinical Practices, Good Laboratory Practices and Good Manufacturing Practices promulgated by the NMPA and other Regulatory Authorities or the ICH; and (c) all applicable industry and trade standards, including the applicable standards of the ISO with, at a minimum, the ISO 9001/9002 quality standards.

"Ascendis FTE Costs" means, for all activities performed by Ascendis or its Affiliates in accordance with the Research and Technical Development Plan or as otherwise directed in writing by the Licensee and agreed to by Ascendis or its Affiliates, the product of: (a) the number of FTEs used by Ascendis or its Affiliates for such activities as set forth in a Research and Technical Development Plan or other written document approved by the Licensee; and (b) the Ascendis FTE Rate. For the avoidance of doubt, the costs of approved service providers fulfilling the obligations of Ascendis or its Affiliates in performing such activities are covered separately under subsection (A) of the "Research and Technical Development Plan Expenses" definition, and are not a part of the Ascendis FTE Costs.

"Ascendis FTE Rate" means (a) if, at the time the applicable Ascendis FTE Costs are incurred, Ascendis owns [***] percent ([***]%) or more of all outstanding preferred shares of Licensee, [***] Euros (€ [***]) per FTE, and (b) if, at the time the applicable Ascendis FTE Costs are incurred, Ascendis owns less than [***] percent ([***]%) of outstanding preferred shares of Licensee, [***] Euros (€ [***]) per FTE; provided in each case of (a) and (b), such amount is fully burdened and includes without limitation, for each FTE, [***], utilities, [***], and a pro rata allocation of general and administrative expenses.

"Ascendis Program IP" means: any Program IP conceived or generated solely by employees, agents or service providers of Ascendis or its Affiliates.

"Ascendis Indemnitee" has the meaning ascribed to it in Clause 15.1.

"Ascendis Patents" means: (a) the patents and patent applications listed in Schedule 1 as of the Effective Date and any conversion, continuation, continuation-in-part, division, provisional or substitution thereof, and any patents issuing thereon, any reissues, re-examinations, confirmations or extensions of such patents (including supplementary protection certificates) and any foreign counterparts of such patent applications and patents in any country in the Territory; and (b) any and all other Patents that are Controlled by Ascendis or its Affiliates as of the Effective Date or at any time thereafter during the term of this Agreement (including without limitation Patents within the Ascendis Program IP or Joint Program IP) that are necessary or useful to make, have made, use, sell, offer for sale or import a Licensed Product.

"Ascendis Technical Information" means: (a) the Technical Information listed in Schedule 2 as of the Effective Date; and (b) any and all other Technical Information that is Controlled by Ascendis or its Affiliates, as of the Effective Date or at any time thereafter during the term of this Agreement (including without limitation Technical Information within the Ascendis Program IP or Joint Program IP), that is necessary or useful to make, have made, use, sell, offer for sale or import a Licensed Product.

"Ascendis Platform Technology" means, as of the Effective Date or at any time thereafter during the term of this Agreement, Ascendis' proprietary chemistry, materials and methodologies for [***] a substrate of interest (e.g., [***]) to various carriers (including [***]) *via* a TransCon Linker, [***].

"Bankrupt Party" has the meaning ascribed to it in Clause 18.3(A).

"Business Day" means a day (other than a Saturday or Sunday) on which banks are open for ordinary face to face banking business in Copenhagen (Denmark), Cayman, China, and San Francisco (California, USA).

"Change of Control" means the occurrence of any of the following events: (a) any Competitor takes control (as the term "control" is defined in the definition of "Affiliate") of Licensee; or (b) Licensee: (i) consolidates with, or merges with or into, a Competitor; or (ii) transfers all or substantially all of its assets to any Competitor.

"Competitor" means a Third Party that [***] commercializing (i.e., as the party having the proprietary rights to and booking sales for, but not as a distributor or wholesaler of) a [***] in [***] as of the date of a Change of Control.

"Confidential Information" means confidential Technical Information (of whatever kind and in whatever form or medium, including copies thereof): (a) disclosed by or on behalf of a Party in connection with this Agreement, whether prior to or during the term of this Agreement and whether disclosed orally, electronically, by observation or in writing; and/or (b) created by, or on behalf of, either Party, or created jointly by the Parties, in the course of this Agreement. "Confidential Information" includes confidential Technical Information regarding such Party's research, development plans, clinical trial designs, preclinical and clinical data, technology, products, business information or objectives and other information of the type that is customarily considered to be confidential information by Parties engaged in activities that are substantially similar to the activities being engaged in by the Parties pursuant to this Agreement. The following shall be deemed the Confidential Information of the Licensee: any and all financial or product pipeline information related to the Licensee provided to Ascendis (whether provided by the Licensee itself or through a Third Party), as well as Licensee Program IP, and the Research and Technical Development Plans. The following shall be deemed the Confidential Information of Ascendis: Ascendis Platform Technology, Ascendis Technical Information, Ascendis Program IP and Ascendis Patents. The following shall be deemed the Confidential Information of both Parties: the terms and conditions of this Agreement.

"Control" or "Controlled" means, with respect to an item of information or Intellectual Property, that a Party has the right, power and legal authority, whether arising by ownership, licence or other authorisation, to disclose, and/or to grant and authorise licences or sub-licences under, such items as required under the terms of this Agreement, without violating the terms of any written agreement with any Third Party under which such Party or its Affiliates first acquired such rights to such item of information or Intellectual Property.

"Diligent Efforts" means with respect to a Party's research, development, and commercialisation of Licensed Products, the level of efforts and resources such Party would typically exert in similar circumstances pursuing the development and commercialisation of a similar product with similar market potential taking into account the stage of development or commercialisation, market potential and market size, the product life cycle, the risk of development or commercialisation of the Licensed Product, the cost effectiveness of efforts or resources, the competitiveness of alternative products that are or are expected to be in the marketplace, the scope and duration of patent rights or other proprietary rights related to the Licensed Product, and the profitability of the Licensed Product [***]. The efforts and resources of each Party's respective Affiliates and Sub-Licensees shall count towards that Party's own Diligent Efforts. Notwithstanding the foregoing, the exercise of diligence by the Licensee shall be determined by judging the Licensee's commercially reasonable efforts taken as a whole [***].

"Effective Date" means the date of this Agreement.

"Endocrinology Disorders" means [***]

"Endocrinology Product" means a product consisting of a substrate of interest (e.g., [***] to a carrier of interest (including [***] via a TransCon Linker for the treatment of Endocrinology Disorders; provided, that [***]

"Entity" means, and includes, any person, firm or company or group of persons or unincorporated body.

"Excluded Indications" means the indications specified in Schedule 3.

"Executives" means the Chief Executive Officer at the Licensee and the Chief Executive Officer at Ascendis.

"FDA" means the US Food and Drug Administration or any successor agency with comparable responsibilities.

"Field" means the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the Excluded Indications.

"Force Majeure" means any circumstances not within the reasonable control of the Party concerned including, without limitation: (a) any strike, lockout or other industrial action, or any shortage of or difficulty in obtaining labour, fuel, raw materials or components; (b) any destruction, temporary or permanent breakdown, malfunction or damage of or to any premises, plant, equipment (including computer systems) or materials; (c) any breach of contract, default or insolvency by or of any Third Party, other than an Affiliate of the Party affected by the force majeure, or an employee or officer of that Party or Affiliate; (d) any action taken by a governmental or public authority imposing an embargo, export or import restriction, rationing, quota or other restriction or prohibition; (e) any civil commotion or disorder, riot, invasion, war, threat of or preparation for war; or (f) any accident, fire, or explosion, (other than in each case, one caused by a breach of contract by or assistance of the Party concerned) storm, flood, earthquake, subsidence, epidemic or other natural physical disaster. Notwithstanding the foregoing, lack of funds, manpower or equipment, interruption or failure of utility service and the fault or misconduct by any personnel engaged by a Party shall not be an event of Force Majeure.

"FTE" means a full time equivalent person year of work (consisting of [***]), prorated on a daily or hourly basis as necessary.

"Good Clinical Practice" means the applicable principles and guidelines for good clinical practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation those set out in the Harmonised Tripartite Guideline for Good Clinical Practice as finalised by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"Good Distribution Practice" means the applicable principles and guidelines for good distribution practice of drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation those set out in Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use, based on Article 84 and Article 85b(3) of Directive 2001/83/EC.

"Good Laboratory Practice" means the applicable principles and guidelines for good laboratory practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation those set out in the OECD Principles of Good Laboratory Practice published by the Organisation for Economic Co-Operation and Development.

"Good Manufacturing Practice" means all applicable principles and guidelines for good manufacturing practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation as specified in the applicable provisions of (i) European Directive 2003/94/EC and further guidance as published by the European Commission in Volume IV of "The rules governing medicinal products in the European Community" and (ii) Title 21 Parts 210 and 211 of the US Code of Federal Regulations (21 CFR, parts 210 and 211).

"ICH" means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"Indemnified Party" has the meaning ascribed to it in Clause 15.3.

"Injector" means any device developed by Ascendis for the purpose of administering TransCon CNP.

"Intellectual Property" means registered or unregistered trademarks, Patents, registered designs, unregistered design rights, business, company, domain or product names, service marks, copyright, know-how, Confidential Information, database rights, any rights in clinical study results, applications for and the right to apply for any of the foregoing, and any similar or analogous rights anywhere in the Territory.

"Intellectual Property Office" means the official local patent, trade mark or other Intellectual Property registry in each part of the Territory responsible for granting, maintaining records of, Patents, trademarks or other Intellectual Property and any instruments made in respect thereof.

"ISO" means the International Organization for Standardization.

"Joint Development Committee" or "JDC" means the joint development committee established under Clause 4.6.

"Joint Program IP" means any Program IP conceived or generated during the course of, and in connection with, this Agreement by employees, agents or service providers of both Ascendis and the Licensee or their respective Affiliates or Sub-Licensees.

"Licensed Product" means a product consisting of C-type natriuretic peptide (CNP) [***] to a carrier [***] by a TransCon Linker and which is developed utilizing the Ascendis Platform Technology, regardless of its finished form, formulation or dosage, alone (the foregoing alone, "TransCon CNP") and, if Ascendis has developed an Injector for use in a clinical trial outside the Territory, also including the Injector.

"Licensed Product Patents" means all Ascendis Patents that claim [***] a Licensed Product in the form as which is concurrently being developed or commercialised, as applicable, by or on behalf of Ascendis or its Affiliates outside of the Territory.

"Licensee Program IP" means: any Program IP conceived or generated solely by employees, agents or service providers of the Licensee or its Affiliates.

"Licensee Indemnitee" has the meaning ascribed to it in Clause 15.2.

"Long-Acting Product" is a product that is intended to be administered to a subject once a week or less frequently than once a week.

"Loss" or "Losses" means any and all losses, liabilities, damages, fines, penalties, costs or expense (including reasonable attorneys' fees and other expenses of litigation).

"Manufacture" or "Manufacturing" means any manufacturing activity of any Licensed Product, or any ingredient thereof, including manufacturing for pre-clinical or clinical use, or commercial sale, testing, handling, packaging and storage, ongoing stability tests and regulatory activities related to any of the foregoing.

"NMPA" means the National Medical Product Administrations of the People's Republic of China, or any successor agency with comparable responsibilities.

"Non-Bankrupt Party" has the meaning ascribed to it in Clause 18.3(A).

"Patents" means any and all: (a) issued patents, including inventor's certificates; (b) patent applications, including any conversion, continuation, continuation-in-part, division, provisional or substitution thereof, and any patents issuing thereon; (c) any reissues, re-examinations, confirmations or extensions of such patents (including supplementary protection certificates); and (d) any foreign counterparts of such patent applications and patents in any country in the Territory.

"Program IP" means any data, results (including all clinical data), improvements and inventions generated by or on behalf of Ascendis or Licensee, or the Parties jointly, in connection with the research, development, Manufacturing, or commercialization activities conducted with respect to the Licensed Product under this Agreement, and all Intellectual Property therein.

"Quarterly Period" means each period of three months commencing on 01 January, 01 April, 01 July and 01 October in a given calendar year.

"Regulatory Approval" means any and all approvals, licenses, registrations, or authorizations of any country, federal, supranational, state, or local regulatory agency, department, bureau, or other government entity that are necessary for the commercialisation of any Licensed Product in a given jurisdiction.

"Regulatory Authority" means any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in any jurisdiction in the Territory involved in the granting of Regulatory Approval for, or involved in the regulation of, pharmaceutical products.

"Research and Technical Development Plan" has the meaning ascribed to it in Clause 4.1.

"Research and Technical Development Plan Activities" means the Research and Technical Development Plan Activities allocated to Ascendis or its Affiliates as set forth in a Research and Technical Development Plan.

"Research and Technical Development Plan Expenses" means the following costs and expenses actually incurred by Ascendis or its Affiliates after the Effective Date in carrying out the Ascendis Research and Technical Development Plan Activities:

(A) the out-of-pocket costs incurred by Ascendis or its Affiliates of having the Research and Technical Development Plan Activities performed by approved service providers (including without limitation Third Party manufacturing organisations) in accordance with the applicable Research and Technical Development Plan;

(B) Ascendis FTE Costs; and

(C) any other costs or expenses specifically identified and included in the applicable Research and Technical Development Plan, which, for the avoidance of doubt, may include, without limitation, pre-paid amounts.

"Share Purchase Agreement" shall mean that certain Share Purchase Agreement dated as of even date herewith, by and among Licensee, Ascendis-China Ltd., Ascendis Pharma A/S, Vivo Plenilune IX Limited, and Sofinnova Venture Partners IX, L.P.

"Shareholders Agreement" means that certain Shareholders Agreement dated as of even date herewith, by and among Licensee, Ascendis-China Ltd., Ascendis Pharma A/S, Vivo Plenilune IX Limited, and Sofinnova Venture Partners IX, L.P.

"SDEA" has the meaning ascribed to it in Clause 9.1.

"Sub-Licensee" means any Entity that has been granted a sub-licence by either Party of its rights granted hereunder in accordance with Clause 2.4.

"Technical Information" means any and all: (a) identifiable know-how, data, inventions, discoveries, findings, methods, proprietary information, processes, techniques, materials and other information and technology (whether patentable or not) including formulae, biological materials, practices, test data (including pharmacological, toxicological and clinical information and related reports, statistical analyses, expert opinions and the like), analytical and quality control data, marketing, pricing, distribution, cost and sales data or descriptions; and (b) all Intellectual Property with respect to the items in subsection (a) above other than Patents. For clarity, as used in this Agreement, the term "Technical Information" excludes Patents.

"Territory" means the People's Republic of China, including Hong Kong, Macao and Taiwan.

"Third Party" means any Entity other than Ascendis or its Affiliates or its Sub-Licensees, or the Licensee or its Affiliates or its Sub-Licensees.

"Third Party Claim" means any action, suit or other proceedings brought by a Third Party.

"TransCon Hydrogel" means Ascendis' proprietary [***] hydrogel containing TransCon Linkers

"TransCon Linker" means Ascendis' proprietary linker used in [***] a substrate of interest to various carriers (including [***], which chemical linker [***].

"TransCon [***]" means Ascendis' proprietary [***]-based carrier containing TransCon Linkers.

"Valid Claim" means any claim of a Patent that has not expired or been disclaimed, abandoned or dedicated to the public, or held revoked, unenforceable, unpatentable or invalid (whether through reexamination, reissue, opposition or otherwise) by a decision of a court or governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time frame allowed for appeal.

"VAT" means value added tax as provided for in the Value Added Tax Act 1994 and legislation supplemental thereto, TVA or any other system of value added tax as provided for in Council Directive 2006/112/EC applied in any Member State of the European Union and any other similar turnover, sales or purchase, tax or duty levied by any other jurisdiction whether central, regional or local.

1.2 **Construction**

In this Agreement where the context admits:

(A) references to any statute or statutory provisions shall be deemed to refer to those provisions as amended or re-enacted or as their application is modified by other provisions from time-to-time and any reference to a statutory provision shall include any subordinate legislation made from time-to-time under that provision;

(B) references to “this Agreement” or to any other agreement or document referred to in this Agreement mean this Agreement or such other agreement or document as may be amended, varied, supplemented, modified or novated from time-to-time, and include the Schedules;

(C) references to Clause(s) and Schedule(s) are references to clause(s) and schedule(s) of and to this Agreement, and each of the Schedules shall have effect as if set out in this Agreement;

(D) references to “proprietary” mean Controlled by a Party, but do not infer any requirement of a Patent;

(E) the headings and sub-headings in this Agreement are inserted for convenience only and shall not affect the construction of this Agreement;

(F) the singular includes the plural and vice versa, and references to the masculine, feminine and the neuter shall include all such genders;

(G) references to any Party include its successors and permitted assigns;

(H) the symbol “€” means the lawful currency of the member states of the European Union that adopt the single currency in accordance with the EC Treaty, known as the “Euro”; and

(I) the symbol “$” means the lawful currency of the United States of America, known as the “US Dollar”.

2. **Grants and Restrictions**

2.1 Ascendis hereby grants to the Licensee an exclusive (even as to Ascendis, and subject to the terms and conditions of this Agreement), royalty-free (in accordance with Clause 7) licence (with the right to grant sub-licences subject to Clause 2.4) under Ascendis Patents and Ascendis Technical Information to develop, Manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize Licensed Product in the Field in the Territory. Licensee has the right to grant sublicenses (through one or more tiers) to its Affiliates that are operating companies for China, Hong Kong or other regions in the Territory and such sublicense agreements will be entered into each within [***] ([***]) days after the applicable operating company is incorporated and becomes operational (each such applicable operating company, a “Sublicensed Affiliate”).

2.2 The Licensee hereby grants to Ascendis a non-exclusive, royalty-free, fully-paid, perpetual, irrevocable license (with the right to grant sub-licences subject to Clause 2.4) under the Licensee Program IP and Licensee’s and its Affiliates’ interest in Joint Program IP, in each case that are Controlled by the Licensee or its Affiliates, to make, have made, use, sell, offer for sale or import Licensed Products in any field of use outside the Territory. Ascendis will have the right to convert such non-exclusive license (in whole or in part, at Ascendis’s discretion) to an exclusive license on commercial reasonable terms to be negotiated between the Parties in good faith.

2.3 **Restrictions**

(A) During the term of this Agreement, neither Ascendis nor its Affiliates shall conduct, or intentionally enable, or participate in, or license or otherwise authorize any Third Party to conduct, enable or participate in, the research, development, Manufacture or commercialisation of any Competing Product in the Territory (whether for its own account or for any Third Party). As used in this Clause 2.4, a "Competing Product" shall mean [***].

(B) During the term of this Agreement, the Licensee covenants that it shall not, and Licensee shall procure that its Affiliates and Sub-Licensees shall not, use or exploit the Ascendis Patents or Ascendis Technical Information otherwise than as expressly permitted under the licences granted to Licensee in Clause 2.1. Further, the Licensee shall not grant any license to any Third Party to Licensee's and its Affiliates interest in (i) Program IP [***] and (ii) any Program IP solely relating to the Ascendis Platform Technology [***], in each case of (i) and (ii), without the prior written consent of Ascendis.

2.4 Each Party agrees that:

(A) any and all sub-licences granted under Clauses 2.1 and 2.2 shall be on terms consistent with the terms of this Agreement, contain obligations on each Sub-Licensee to perform and observe terms and conditions similar to those contained herein so far as the same are applicable;

(B) it shall be liable to the other Party for any acts and omissions of its Sub-Licensee that cause any breach of the provisions of this Agreement; and

(C) it shall, within [***] ([***]) days of the grant of each sub-licence, provide the other Party with [***], provided that [***] from such sub-licence: [***].

2.5 Ascendis shall [***] not to commit any acts or omissions that could cause a material breach of any licence agreement pursuant to which Ascendis has rights to Intellectual Property that it has sub-licensed to the Licensee under this Agreement, such that its Third Party licensor terminates or amends such licence agreement in any way that materially adversely affects a licence or other right granted to the Licensee under this Agreement that is used in a Licensed Product being developed (including under an active Research and Technical Development Plan) or commercialised by the Licensee. Ascendis shall not exercise any rights it may have with respect to any such licence agreement, or amend, terminate, or waive any of its rights under such licence agreement in any way that materially adversely affects a licence or other right granted to the Licensee under this Agreement that is used in a Licensed Product being developed (including under an active Research and Technical Development Plan) or commercialised by the Licensee.

2.6 Only the licences granted or retained pursuant to the express terms of this Agreement shall be of any legal force or effect. No other licence rights shall be created by implication, estoppel or otherwise under this Agreement.

2.7 Each Party shall procure that its Affiliates shall comply with the terms and conditions of this Agreement and shall be liable to the other Party for any acts or omissions of such Affiliates which are not in compliance with the terms and conditions of this Agreement.

2.8 During the term of this Agreement, prior to engaging in substantive discussions with a Third Party regarding the license to such Third Party by Ascendis or its Affiliates under the Ascendis Platform Technology of [***] commercialise Endocrinology Product(s) in the Territory, either by license, option, or otherwise (a "ROFN Opportunity"), Ascendis shall notify Licensee thereof, except to the extent Ascendis cannot grant to Licensee or its Affiliates any rights to such Endocrinology Products in the Territory in light of restrictions imposed on Ascendis or its Affiliates under agreements by and between Ascendis or its Affiliates (on the one hand) and a Third Party (on the other hand) existing as of the "Initial Closing Date" (as such term is defined in the Share Purchase Agreement. No later than [***] ([***]) Business Days after Licensee's receipt of such notice, Licensee shall notify Ascendis whether Licensee wishes to enter into negotiations with Ascendis to negotiate an agreement for Licensee to obtain the right corresponding to such ROFN Opportunity on reasonable commercial terms to be agreed on in good faith ("ROFN License Agreement"). If Licensee does not timely notify Ascendis that it wishes to negotiate for the ROFN Opportunity, or notifies Ascendis that it is not interested in the ROFN Opportunity, Ascendis shall be free to engage with Third Parties discussions of such ROFN Opportunity, and Licensee shall have no further rights under this Clause 2.8 with respect to such ROFN Opportunity. If Licensee timely notifies Ascendis it wishes to negotiate an agreement for such ROFN Opportunity, the Parties shall enter into good faith negotiations not to exceed [***] ([***]) days with the goal of finalizing the terms of and executing such ROFN License Agreement. If after the expiration of such [***] ([***])-day period (the "ROFN Negotiation Stop Date"), the Parties have not executed such ROFN License Agreement, Ascendis shall be free to engage with Third Parties discussions of such ROFN Opportunity [***], and Licensee shall have no further rights under this Clause 2.8 with respect to such ROFN Opportunity. Notwithstanding any other provision of this Clause 2.8, in no event shall this Clause 2.8 limit in any way the ability of Ascendis or its Affiliates to engage in discussions with a Third Party for [***] to such Third Party under the Ascendis Platform Technology to [***] commercialise an Endocrinology Product so long as such discussions are not in conflict with Ascendis's obligations under Clause 2.3(A), and any such discussions shall not be deemed a "ROFN Opportunity" for which this Clause 2.8 applies.

2.9 In the event that Ascendis discontinues the development or commercialization of Licensed Product outside the Territory, or if Licensee discontinues the development or commercialization of Licensed Product in the Territory for safety, efficacy and/or regulatory reasons relating to Licensed Product (a "Qualifying Discontinuance"), Ascendis or Licensee, as the case may be, shall promptly inform the other Party of such Qualifying Discontinuance and shall provide relevant data and documentation which forms the basis of such decision to the other Party. In the event of a Qualifying Discontinuance, upon the Licensee's request, Ascendis shall provide to the Licensee [***] for its other Endocrinology Products which are [***] and for which Ascendis has not granted any Third Party [***] in the Territory, and the Licensee may elect to (i) continue activities with respect to the relevant Licensed Product in the Territory, or (ii) substitute the relevant Licensed Product with one of such other Endocrinology Products, [***], in which event such Endocrinology Product will become a Licensed Product and the Parties shall execute an amendment to this Agreement to memorialize the same. Further, if Licensee requires any technology transfer in connection with such substitution under clause (ii) of the preceding sentence, the Parties [***] the scope and timing for such transfer, as well as FTE-based payments to be made to Ascendis with respect to such transfer activities.

3. **Technical Information and Patents**

3.1 Within [***] ([***]) days of the Effective Date, Ascendis shall deliver and provide to the Licensee the items of Ascendis Technical Information listed in Schedule 2.

3.2 Ascendis shall use its Diligent Efforts to provide the Licensee with any additional Technical Information that is not specified in Schedule 2 but is Controlled by Ascendis and/or its Affiliates relating to the Ascendis Technical Information or Ascendis Platform Technology during the term of this Agreement that is necessary or useful for the Licensee to make, have made, use, sell, offer for sale or import Licensed Product in the Field in the Territory. [***].

3.3 Upon the Licensee's written request, but in no event more than [***] during the term of this Agreement, Ascendis shall provide, [***] to the Licensee a written update (as of the date the request is received by Ascendis) of the Licensed Product Patents in Schedule 1 and/or Ascendis Technical Information in Schedule 2.

4. **Development and Commercialisation**

4.1 Within [***] days following the Effective Date, the Parties shall agree to a research and technical development plan (the "Research and Technical Development Plan") that sets forth the Parties' respective Research and Technical Development Plan Activities, which may be amended from time to time by the JDC in accordance with this Agreement. The Parties shall perform and complete, or cause the performance and completion of, their respective Research and Technical Development Plan Activities, and deliver to each other a summary of the results (including raw data if reasonably requested by a Party), samples and reports arising therefrom in accordance with each Research and Technical Development Plan within [***] ([***]) days following completion thereof.

4.2 The Licensee shall provide Ascendis with a draft of each Research and Technical Development Plan. The Licensee shall consider, in good faith, any comments regarding each draft Research and Technical Development Plan that Ascendis provides to the Licensee within [***] ([***]) days of Ascendis' receipt of such draft Research and Technical Development Plan. In addition, the Licensee shall keep Ascendis informed of the progress of the development of each Licensed Product against the applicable Research and Technical Development Plan at each meeting of the JDC pursuant to Clause 4.6(A).

4.3 The Licensee shall be solely responsible for any clinical trial activities carried out as part of its development and commercialisation activities in the Territory.

4.4 The Licensee shall use Diligent Efforts to develop and commercialise Licensed Product in the Field in the Territory.

4.5 Each Party shall conduct all development of Licensed Product in compliance with current Good Laboratory Practice, Good Clinical Practice and Good Manufacturing Practice, in each case, where applicable. Neither Party shall use any person that has been debarred, disqualified or banned from practising medicine to perform activities under this Agreement, and each Party shall immediately notify the other Party in writing if any person performing activities under this Agreement is disqualified, debarred or banned from practising medicine.

4.6 **Joint Development Committee**

(A) **Formation of JDC**

Promptly after the Effective Date, the Parties will form a Joint Development Committee comprised of three (3) representatives of Ascendis and three (3) representatives of the Licensee for the first Research and Technical Development Plan (and will promptly form a JDC following agreement between the Parties in relation to each additional Research and Technical Development Plan). Ascendis agrees that it shall not have the right to nominate representatives of the Licensee to the JDC notwithstanding its ownership in the Licensee.

One representative of the Licensee at the JDC will be selected to act as the chairperson of the JDC. The JDC will meet at least [***] ([***]) times per year during the term of a Research and Technical Development Plan. Such meetings may be conducted by videoconference, teleconference or in person, as agreed by the Parties. The JDC will agree upon the time and location of the meetings. The chairperson, or his or her designee, will circulate an agenda for each meeting approximately [***] before the date scheduled for the meeting, and will include all matters requested to be included on such agenda by either Party. The chairperson, or his or her designee, will take complete and accurate minutes of all discussions occurring at the JDC meetings and all matters decided upon at the meetings except that matters reflecting legal advice of counsel will not be included in such minutes. A copy of the draft minutes of each meeting will be provided to each Party by the chairperson, or his or her designee, after each meeting, and such minutes will be reviewed by the JDC members, any needed changes discussed and final minutes agreed to and provided to each Party within [***] ([***]) days after each meeting unless otherwise agreed. A reasonable number of additional representatives of a Party may attend meetings of the JDC in a non-voting capacity. Each Party is responsible for its personnel and travel costs and expenses associated with attending meetings.

(B) **JDC functions and powers**

The responsibilities of the JDC will be as follows:

(1) encouraging and facilitating communication between the Parties with respect to the development of Licensed Product(s)) and the Research and Technical Development Plan Activities;

(2) [***] the applicable Research and Technical Development Plan's objectives, goals and schedules, and reviewing and approving amendments to the applicable Research and Technical Development Plan, [***]

(3) [***], discussing and [***] the progress of the development of Licensed Product, each Party's progress with respect to the Research and Technical Development Plan Activities for which it is responsible and each Party's diligence in carrying out its responsibilities under the applicable Research and Technical Development Plan; and

(4) carrying out the other duties and responsibilities described for it in this Agreement.

(C) **JDC decision making**

(1) All decisions of the JDC will be made by unanimous vote, with each of Ascendis and Licensee having one vote and the decisions will be recorded in the JDC minutes. If after reasonable discussion and consideration of each of the Parties' views on a particular matter before the JDC, the JDC is unable to reach a decision by unanimous vote on that matter, then [***]

The JDC shall not have any authority other than that expressly set forth above and, specifically, shall have no authority: (x) to amend or interpret this Agreement; (y) to determine whether or not a Party has met its diligence or other obligations under the Agreement; or (z) to determine whether or not a breach of this Agreement has occurred.

(D) **Termination of JDC**

The JDC shall terminate in respect of a Research and Technical Development Plan upon completion by both Parties of their respective Research and Technical Development Plan Activities, unless the Parties otherwise agree.

5. **Manufacturing**

5.1 Concurrently with the execution of this Agreement, the Parties have entered into that certain clinical supply agreement (the "Clinical Supply Agreement") pursuant to which Ascendis will supply Licensed Product to Licensee for Licensee's conduct of clinical trials for the Licensed Product in the Territory on the terms and conditions set forth in the Clinical Supply Agreement. The Parties shall discuss and negotiate in good faith the terms and conditions for the supply by Ascendis of Licensed Product to the Licensee for commercial use upon the written request of Licensee, and in any event starting no later than the date that is [***] ([***]) days after the initiation of the first pivotal clinical trial for the Licensed Product conducted by or behalf of Licensee in the Field and in the Territory.

5.2 The Licensee shall, and it shall procure that its Affiliates and any Sub-Licensees shall:

(A) [***] relating to the sale of Licensed Product comply with Applicable Laws and are marked, where required, with all relevant patent numbers; and

(B) conduct all packaging and distribution in accordance with current Good Manufacturing Practice and Good Distribution Practice.

6. **Regulatory**

6.1 The Licensee shall have the sole responsibility for obtaining and maintaining, and shall own, all Regulatory Approvals for Licensed Product developed under this Agreement from Regulatory Authorities in each of the jurisdictions in the Territory in the Field.

6.2 Ascendis hereby grants to the Licensee, its Affiliates and Sub-licensees the right to access, reference and utilize any data (including clinical trial data) or regulatory filings generated and/or filed by or on behalf of Ascendis or its Affiliates or other licensees (in each case, to the extent Controlled by Ascendis or its Affiliates) with respect to Licensed Product(s)) in connection with the development, Manufacturing and commercialisation by the Licensee, its Affiliates and Sub-licensees of Licensed Product(s) in the Territory, free of additional charge, as set forth herein. Upon written request from Licensee to be provided access to any such information, Ascendis shall provide such access to Licensee within a reasonable time frame, taking into account the development and regulatory activities conducted by or on behalf of Ascendis for the Licensed Products outside of the Territory. Ascendis hereby represents and warrants that, as of the Effective Date, it and/or its Affiliates Control all data and regulatory filings generated and/or filed by or on behalf of Ascendis or its Affiliates or other licensees with respect to the Licensed Product and Ascendis has the right to grant the right to access, reference and utilization to Licensee, its Affiliates and Sub-licensees thereto. During the Term, Ascendis and/or its Affiliates shall maintain the right to all data and regulatory filings generated and/or filed by or on behalf of Ascendis or its Affiliates or other licensees with respect to the Licensed Product (including by reserving the rights from any Third Party generating, filing and/or having rights to any and all such data and/or regulatory filings) so that Ascendis and/or its Affiliates retains Control of such data and regulatory filings and can grant the right to access, reference and utilization to Licensee, its Affiliates and Sub-licensees under this Section 6.2.

6.3 The Licensee hereby grants to Ascendis the right to access, reference and utilize any data (including clinical trial data) or regulatory filings generated and/or filed by or on behalf of the Licensee or its Affiliates or sublicensees (in each case, to the extent Controlled by Licensee or its Affiliates) with respect to Licensed Product(s) in connection with the development, Manufacturing and commercialisation by Ascendis, its Affiliates or other licensees of Licensed Product(s) outside the Territory, free of additional charge, as set forth herein. Upon written request from Ascendis to be provided access to any such information, Licensee shall provide such access to Ascendis within a reasonable time frame, taking into account the development and regulatory activities conducted by or on behalf of Licensee for the Licensed Products in the Field in the Territory. During the Term, Licensee and/or its Affiliates shall maintain the right to all data and regulatory filings generated and/or filed by or on behalf of Licensee or its Affiliates or Sub-licensees with respect to the Licensed Product (including by reserving the rights from any Third Party generating, filing and/or having rights to any and all such data and/or regulatory filings) so that Licensee and/or its Affiliates retains Control of such data and regulatory filings and can grant the right to access, reference and utilization to Ascendis, its Affiliates and other licensees under this Section 6.2.

6.4 The Licensee undertakes to comply, and to procure that its Sub-Licensees and contractors comply, with all requirements of Regulatory Authorities and/or Applicable Law and relevant guidance.

6.5 Ascendis shall provide assistance and information as reasonably requested by the Licensee in support of such regulatory activities[***].

7. **Payments**

7.1 **Upfront**

As a one-time, non-refundable consideration of the rights and licence granted by Ascendis to Licensee under this Agreement, Licensee shall issue and transfer to Ascendis [***] Series A-1 Preferred Shares in VISEN Pharmaceuticals, corresponding to a total value of US[***] at the Effective Date.

7.2 **Research and development funding**

The Licensee shall pay or reimburse (as applicable) Ascendis for the Research and Technical Development Plan Expenses in accordance with the schedule set forth in the Research and Technical Development Plans.

7.3 **Taxes**

In the event that the Licensee is required, under applicable laws, to withhold any deduction or tax from any payment due to Ascendis under this Agreement, such amount shall be deducted from the payment to be made by the Licensee, paid to the proper taxing authority, provided that the Licensee shall take reasonable and lawful actions to avoid and minimise such withholding and promptly notify Ascendis so that Ascendis may take lawful actions to avoid and minimise such withholding. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time-to-time in effect.

All sums payable by the Licensee under or pursuant to this Agreement [***] (if applicable). The taxable supply of services made under or in connection with this Agreement by Ascendis to the Licensee are [***]. The Parties agree that they will undertake commercially reasonable efforts to minimize or eliminate any VAT liability, including but not limited to [***].

7.4 **Interest**

Where any fees, milestones or other sums payable by the Licensee to Ascendis hereunder remain unpaid after the date on which they became due, the Licensee shall pay to Ascendis interest calculated from the date upon which the sums became due until payment thereof at the rate, to the extent permitted by applicable law, equal to the average one-month US Dollar London Interbank Offered Rate (LIBOR) as determined for each Quarterly Period on the last Business Day of such Quarterly Period (it being understood that if such rate is below zero percent (0%) for any period it shall be deemed to be zero percent (0%) for such period for the purposes of this Clause 7.4) plus [***] percent ([***]%).

8. **Records and Auditing**

8.1 Each Party will maintain complete and accurate books, records and accounts used for the determination of any payment obligations under this Agreement, which books, records and accounts will be retained by such Party until [***] ([***]) years after the end of the period to which such books, records and accounts pertain. The Licensee shall make such books, records and accounts available to Ascendis for an additional [***] ([***]) years if reasonably available and required by the applicable tax authority.

9. **Pharmacovigilance**

9.1 After the execution of this Agreement, the Parties shall promptly, and in any event before the Licensee starts any clinical development activities, agree on the terms of a safety data exchange agreement (the "SDEA") for the collection, reporting and exchange of safety information. The scope of the SDEA shall also include the Licensee's Affiliates and Sub-Licensees, as applicable.

9.2 Each Party shall notify the other Party of any "serious adverse experience" or "unexpected adverse experience" (as defined below) and will manage the same, both in accordance with the terms of the SDEA. For the purpose of this Clause 9.2, "serious adverse experience" and "unexpected adverse experience" shall have the meaning assigned by relevant regulations (to the extent applicable). To the extent relevant regulations require harmonisation or are not applicable, then each of the foregoing terms shall be as defined in the SDEA.

10. **Confidentiality**

10.1 During the term of this Agreement, and for a period of [***] ([***]) years thereafter, the Licensee agrees to keep secret Ascendis' Confidential Information, to use the same exclusively as permitted under this Agreement, and to disclose the same only to those of its employees, contractors, consultants, Affiliates and Sub-Licensees to whom and to the extent that such disclosure is reasonably necessary in order to exercise its rights and perform its obligations under this Agreement.

10.2 During the term of this Agreement, and for a period of [***] ([***]) years thereafter, Ascendis agrees to keep secret the Licensee's Confidential Information, to use the same exclusively as permitted under this Agreement, and to disclose the same only to those of its employees, contractors, Affiliates, Sub-Licensees and licensees to whom and to the extent that such disclosure is reasonably necessary in order to exercise its rights and perform its obligations under this Agreement.

10.3 Each Party shall procure that all its employees, contractors, Affiliates and Sub-Licensees who have access to any Confidential Information of the other to which the obligations of Clauses 10.1 or 10.2 as the case may be apply, shall be made aware of, subject to, and comply with those obligations. Without limiting the foregoing, each Party shall take at least those measures it employs to protect its own confidential information of a similar nature to protect the other Party's Confidential Information, but in any event no less than reasonable care.

10.4 The foregoing obligations of Clauses 10.1 and 10.2 shall not apply to any Confidential Information of the disclosing Party which:

(A) prior to the recipient Party's receipt thereof from the disclosing Party, was in the possession of the recipient Party without any breach of confidentiality and at its free disposal;

(B) is subsequently lawfully disclosed to the recipient Party without any breach of confidentiality by an independent Third Party, and at the recipient Party's free disposal;

(C) is or becomes generally available to the public through no act or default of the recipient Party or its agents, contractors or employees; or

(D) is independently developed by the receiving Party without the benefit of any Confidential Information disclosed hereunder, as demonstrated by documented evidence prepared contemporaneously with such independent development.

10.5 Notwithstanding the foregoing, a Party and its Affiliates and Sub-Licensees may use and disclose the Confidential Information of the other Party:

(A) if it is required to be disclosed by law, regulation or action of any governmental agency or authority, including as may be required in connection with any filings made with, or by the disclosure policies of a major stock exchange; provided that the Party seeking to disclose the Confidential Information of the other Party: (i) promptly informs the other Party (prior to making any such disclosures, if practicable) and cooperates with the other Party in seeking a protective order or other appropriate remedy (including redaction); and (ii) whenever it is possible to obtain confidential treatment, request confidential treatment of such information;

(B) as reasonably necessary to obtain or maintain any Regulatory Approval, including to conduct preclinical studies and clinical trials and for pricing approvals, for any Licensed Product, provided that, the disclosing Party shall use commercially reasonable efforts to limit disclosure of the Confidential Information outside such regulatory agency and to otherwise maintain the confidentiality of the Confidential Information; or

(C) as reasonably necessary to exercise its rights or fulfil its obligations under this Agreement.

10.6 The Licensee and its Affiliates and Sub-Licensees may disclose the Confidential Information of Ascendis to contractors, consultants and other service providers in connection with the development or Manufacture of Licensed Product(s) under conditions of confidentiality at least as restrictive as those contained in this Clause 10 and/or as is standard for similar deals in the biotechnology industry.

10.7 If a Party concludes that a copy of this Agreement must be filed with the United States Securities Exchange Commission or other regulatory agency ("SEC") (or equivalent foreign agency or a securities exchange), such Party will use all reasonable efforts to provide the other Party with a copy of this Agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, and to provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions. The filing Party will take such other Party's reasonable comments into consideration before filing the Agreement.

10.8 Each Party ("Publishing Party") shall submit to the other Party manuscripts, including abstracts, and texts of poster presentations and other external presentations containing the other Party's Confidential Information at least [***] ([***]) days prior to presentation or submission for publication for purposes of allowing the other Party to comment on the manuscript or text; provided that the other Party may require the Publishing Party, by giving notice in writing to the Publishing Party within [***] ([***]) days of the receipt of such manuscript, abstract, text or other external presentations from the Publishing Party to redact certain information or delay submission for publication or presentation of such manuscript, abstract, text or other external presentation if, in the reasonable opinion of the other Party such delay is necessary in order to permit the filing of any patent application or to protect the other Party's Confidential Information contained in such manuscript, abstract, text or other external presentation.

10.9 The Licensee, in accordance with its internal policies and procedures, shall have the right to publish all studies, clinical trials and results thereof on the clinical trial registries that are maintained by or on behalf of the Licensee. Ascendis shall not publish any studies, clinical trials or results thereof on its clinical trial registry, provided however, that Ascendis may include on Ascendis' clinical trial registry a link to the Licensee's clinical trial registry.

10.10 Notwithstanding the foregoing, each Party shall have the right to disclose the terms and conditions of this Agreement: (i) in confidence (i.e., pursuant to a written confidentiality agreement containing terms at least as stringent as those contained in this Agreement) to any bona fide potential or actual investor, investment banker, auditor, counsel, acquirer or merger target; and (ii) subject to the prior written consent of the other Party, such consent not to be unreasonably withheld, for the purpose of a public offering or private placement of shares and/or securities.

11. **Intellectual Property**

11.1 All Patents and Technical Information and other Intellectual Property owned or Controlled by a Party prior to the Effective Date shall remain owned or Controlled by the respective Party.

11.2 Ascendis and the Licensee acknowledge and agree that as between them:

(A) Ascendis (or its Affiliates) shall own all right, title and interest in and to any and all Ascendis Patents (except for Ascendis Patents within the Joint Program IP), Ascendis Technical Information (except for Ascendis Technical Information within the Joint Program IP) and Ascendis Program IP;

(B) the Licensee shall own all right, title and interest in and to any and all Licensee Program IP; and

(C) the Licensee and Ascendis (or its Affiliates) shall each own an undivided fifty percent (50%) right, title and interest in and to any and all Joint Program IP. For the avoidance of doubt, subject to the licences granted under this Agreement, each Party shall be free to exploit, transfer or encumber its own interest in the Joint Program IP without the consent of, and without accounting to, the other Party. For those jurisdictions where a specific license is required for a joint owner of Joint Program IP to practice such Joint Program IP in such jurisdictions: (i) Ascendis hereby grants to Licensee a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable license under Ascendis's right, title and interest in and to all Joint Program IP to use such Joint Program IP in accordance with the terms of this Agreement; and (ii) Licensee hereby grants to Ascendis a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable license under Licensee's right, title and interest in and to all Joint Program IP to use such Joint Program IP in accordance with the terms of this Agreement. Each Party shall promptly notify the other Party after it first learns of the conception of a Joint Program IP by such Party, its employees, officers, or independent contractors, and provide the other Party with a detailed report of the underlying data, results, experimental procedures related to, and inventors of, such Joint Program IP.

11.3 Notwithstanding the foregoing, [***].

12. **Prosecution, Maintenance and Defence**

12.1 Subject to Clause 12.4, Ascendis shall, at its own expense and in its sole discretion, have the right to file, prosecute, maintain and defend the Ascendis Patents that are not Joint Program IP Patents (as defined in Clause 12.3(A) (including without limitation Licensed Product Patents as well as any Ascendis Patent claiming Ascendis Platform Technology that are not Joint Program IP Patents). Solely with respect to the Licensed Product Patents in the Territory that are not within the Joint Program IP, Ascendis will promptly provide the Licensee with drafts of all proposed filings and correspondence (including without limitation the initial application as well as any material correspondence with any Intellectual Property Office in the Territory related to any filings) in a manner that allows the Licensee a reasonable opportunity for review and comment (and in any event no less than [***] ([***]) days, if and when possible) before such filings are due. Ascendis will consider all of the Licensee's reasonable suggestions, recommendations and instructions concerning the preparation, filing, prosecution, defence and maintenance of any such Patents (including without limitation any suggestion or recommendation [***]), provided that such reasonable suggestions, recommendations and instructions are provided to Ascendis within [***] ([***]) days of the Licensee receiving any such proposed filings and correspondence. If Ascendis does not wish to file, prosecute or maintain any such Licensed Product Patent which is not within the Joint Program IP, or if Ascendis wishes to allow any such Patent to lapse, in each case, solely within the Territory, then [***], Ascendis shall notify Licensee in writing of such decision at least [***] ([***]) days prior to any action relating to such Patent is required, and Licensee shall then have the option, at its sole discretion, to file, prosecute, and/or maintain such Patent, at its sole cost and expense.

12.2 Subject to Section 12.4, the Licensee shall, at its own expense and in its sole discretion, have the right to file, prosecute, maintain and defend any Patent within the Licensee Program IP. If Licensee does not wish to file, prosecute or maintain any such Patent within the Licensee Program IP, or if Licensee wishes to allow any such Patent to lapse, in each case, solely outside of the Territory, then [***], Licensee shall notify Ascendis in writing of such decision at least [***] ([***]) days prior to any action relating to such Patent is required, and Ascendis shall then have the option, at its sole discretion, to file, prosecute, and/or maintain such Patent, at its sole cost and expense.

12.3 **Joint Program IP**

(A) Subject to Clause 12.4, the Prosecuting Party (as defined below) shall select outside patent counsel ("Outside Patent Counsel") at its sole discretion to file, prosecute and maintain any Patent within the Joint Program IP in the joint names of the Parties ("Joint Program IP Patent"). [***] shall have the first right, at its sole expense and in its sole discretion, to engage Outside Patent Counsel to file, prosecute and maintain all Joint Program IP Patents, and [***] shall have the backup right to file, prosecute, and maintain such Joint Program IP Patents in the Territory in accordance with Clause 12.3(C). The Party that exercises its right to file, prosecute and maintain a particular Joint Program IP Patent in accordance with this Clause 12.3 shall be referred to as the "Prosecuting Party".

(B) With respect to Joint Program IP Patents, the Prosecuting Party will (or will cause Outside Patent Counsel to) promptly provide the other Party with drafts of all proposed filings and correspondence (including without limitation the initial application as well as any material correspondence with any Intellectual Property Office related to any filings) in a manner that allows the other Party a reasonable opportunity for review and comment (and in any event no less than [***] ([***]) days, if and when possible, before such filings are due). The Prosecuting Party will (or will cause Outside Patent Counsel to) consider all of the other Party's reasonable suggestions, recommendations and instructions concerning the preparation, filing, prosecution, defence and maintenance of any such Joint Program IP Patents (including without limitation any suggestion or recommendation [***]), provided that such reasonable suggestions, recommendations and instructions are provided to the Prosecuting Party (or Outside Patent Counsel) within [***] ([***]) days of the other Party receiving any such proposed filings and correspondence.

(C) If [***] as the Prosecuting Party elects: (1) not to file, prosecute or maintain a Joint Program IP Patent (whether in one or more jurisdictions); or (2) to allow any such Patent to lapse or become abandoned or unenforceable, in each case, in accordance with Clause 12.3(A), then [***] shall notify [***] in writing at least [***] ([***]) days prior to the lapse or abandonment of any such Patent. Thereafter, [***] may, but is not required to, undertake, at its sole expense and in its sole discretion, and using Outside Patent Counsel, the prosecution and maintenance of such Joint Program IP Patent, but solely within the Territory, and in such case, [***] shall become the Prosecuting Party with respect to such Patent in the Territory.

12.4 Notwithstanding any other provision of this Clause 12, [***]

12.5 The Parties agree to cooperate reasonably in the filing, prosecution and maintenance of all Patents as set forth under this Clause 12 including providing relevant Technical Information to the prosecuting Party (as determined in accordance with this Clause 12), obtaining and executing necessary powers of attorney and assignments by the named inventors, obtaining execution of such other documents which may be needed in the filing, prosecution and maintenance of each such Patent, and, as requested, updating each other regarding the status of each such Patent, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession and Control that is reasonably necessary to prosecute and maintain such Patents.

13. **Enforcement of Patent Rights and Defence of Third Party Claims**

13.1 **Infringement by a Third Party**

(A) In the event of Ascendis or the Licensee becoming aware of any suspected infringement or any unauthorised use by a Third Party of any of the Ascendis Patents, Ascendis Technical Information, Ascendis Program IP, Licensee Program IP, and/or the Joint Program IP in the Field in the Territory, the Party becoming aware of the same shall promptly notify the other Party.

(B) Where such suspected infringement or unauthorised use is of the Ascendis Patents or Ascendis Technical Information (including those within the Joint Program IP and/or Ascendis Program IP), in each case (i) outside the Territory, or (ii) inside the Territory but outside the Field, Ascendis shall, at its own expense, have the exclusive right, but not the obligation, to take or threaten any legal action that it deems appropriate to halt such suspected infringement and to retain any amounts recovered in respect of such suspected infringement or unauthorised use. Termination and/or settlement of the litigation are at the sole discretion of Ascendis (i.e., without the prior consent of the Licensee), provided such termination or settlement does not impose a liability (monetary or otherwise) on Licensee or limit the rights of Licensee under this Agreement, or otherwise materially impair Licensee's rights in the relevant Ascendis Patent in each case without Licensee's prior written consent.

(C) Where such suspected infringement or unauthorised use is of the Ascendis Patents Ascendis Technical Information (including those within the Joint Program IP and/or any Ascendis Program IP), in each case in the Field in the Territory, the Licensee shall, at its own expense, have the first right, but not the obligation to take or threaten any legal action that it deems appropriate to halt such suspected infringement (provided that [***]). Each Party shall retain the following percent of any remaining amounts recovered in respect of such suspected infringement or unauthorised use after the Licensee has recouped its expenses: the Licensee shall retain [***] percent ([***]%) and Ascendis shall retain [***] percent ([***]%). Termination and/or settlement of the litigation are at the sole discretion of the Licensee (i.e., without the prior consent of Ascendis), provided such termination or settlement does not impose a liability (monetary or otherwise) on Ascendis or limit the rights of Ascendis under this Agreement, or otherwise materially impair Ascendis's rights in the relevant Ascendis Patent in each case without Ascendis's prior written consent.

(D) If Ascendis wishes to take or threaten legal action and the Licensee has the first right to do so under Clause 13.1(C), but does not do so within [***] ([***]) days of becoming aware of potential infringement, then Ascendis may take or threaten such legal action and the Licensee shall, at Ascendis' request, lend its name where necessary or desirable to proceedings relating to such action and provide reasonable assistance in such proceedings. In such circumstances, Ascendis shall control the conduct of the action but shall consult the Licensee in good faith with regard to significant decisions. Each Party shall retain the following percent of any remaining amounts recovered in respect of such suspected infringement or unauthorised use after Ascendis has recouped its expenses: Ascendis shall retain an amount equal to [***] percent ([***]%) and the Licensee shall retain the remaining [***] percent ([***]%). Termination and/or settlement of the litigation are at the sole discretion of Ascendis (i.e., without the prior consent of the Licensee).

(E) Each Party shall provide to the Party enforcing any such rights under this Clause 13.1 reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by Applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any important aspects of such enforcement, including determination of litigation strategy and filing of important papers to the competent court.

13.2 **Defence of Third Party Claims**

(A) In the event that the development or commercialisation of a Licensed Product results in action by a Third Party against a Party (or its Affiliates or Sub-Licensees) for infringement or unauthorised use of Intellectual Property or confidential information anywhere in the Territory, such Party shall promptly notify the other Party in writing.

(B) Each Party (or its Affiliates or Sub-Licensees) against whom such action is brought shall: (i) have the right but not the obligation to defend such action; (ii) have the right to be represented by separate legal advisors; (iii) keep the other Party informed of, and assist and co-operate with the other Party in, any such action; and (iv) bear its own costs.

14. **Warranties**

14.1 Each Party warrants to the other Party that it:

(A) is free to enter into this Agreement and to carry out its obligations hereunder without violating any obligation owed by it or any of its Affiliates to any Third Party;

(B) shall not, during the existence of this Agreement, enter into any assignments, licences, obligations, charges or assignments, either written, oral or implied, which are or shall be inconsistent with this Agreement;

(C) has obtained all necessary corporate approvals to enter into and execute this Agreement;

(D) has never been debarred, disqualified or banned from practising medicine and that it is not under investigation by any Regulatory Authority for debarment, disqualification or any similar regulatory action in any country.

14.2 Ascendis represents and warrants to the Licensee that, as of the Effective Date, Ascendis:

(A) Controls the Ascendis Patents and Ascendis Technical Information in the Field in the Territory;

(B) has the right to grant to the Licensee the rights and licences granted to the Licensee under the terms and conditions of this Agreement,

(C) has the right to provide and disclose to the Licensee the Ascendis Technical Information that it provides or discloses to the Licensee under the terms and conditions of this Agreement;

(D) itself and its employees have not received notice of any actions, lawsuits, claims or arbitration or material adverse proceedings (other than on-going routine patent prosecution matters) in any way relating to the Ascendis Patents, Ascendis Technical Information or Ascendis Platform Technology; and

(E) is not, to [***] its knowledge, aware that the use of Licensed Product Patents in Schedule 1, the Ascendis Patents existing as of the Effective Date, and/or Ascendis Technical Information listed in Schedule 2, for development or commercialisation of a Licensed Product infringes any Third Party's Patent.

(F) there are no patents, patent applications or Technical Information that are owned or in-licensed by Ascendis and/or its Affiliates that Ascendis and/or its Affiliates do not Control and are not included in the license granted to Licensee under this Agreement, which would be infringed by or would otherwise cover the development, manufacture and/or commercialization of the Licensed Product in the Field in the Territory. During the Term, Ascendis and/or its Affiliates shall maintain the Control of patents, patent applications and/or Technical Information that are then-owned or then-in-licensed by Ascendis and/or its Affiliates that would be infringed by or would otherwise cover the development, manufacture and/or commercialization of the Licensed Product in the Field in the Territory (including by reserving such rights from any Third Party carrying out the development, manufacture and/or commercialization of the Licensed Product on behalf of or under a license from Ascendis or its Affiliates) so that such patents, patent applications and/or Technical Information are included in the license granted to Licensee hereunder; provided, that for clarity this provision shall not be deemed to impose any obligation on Ascendis to obtain ownership or license rights to any patents, patent applications, Technical Information, or intellectual property rights of any Third Party.

14.3 EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO INTELLECTUAL PROPERTY RIGHTS OR CONFIDENTIAL INFORMATION SUPPLIED BY IT TO THE OTHER PARTY HEREUNDER, AND EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT.

15. **Indemnification**

15.1 Except as provided in Clause 15.2 below, the Licensee shall indemnify, defend and hold harmless Ascendis and its Affiliates, and their respective directors, officers, employees and agents (each an "Ascendis Indemnitee") from and against all Losses arising out of or resulting from any Third Party Claims to the extent such Losses result from or arise out of: (a) the activities performed by the Licensee in connection with the exercise of its rights or obligations under this Agreement (including the exploitation of the Licensed Product(s) in the Territory); (b) breach by the Licensee of the representations and warranties provided in Clause 14; (c) gross negligence, recklessness or wilful misconduct by the Licensee; or (d) violation of Applicable Law by the Licensee. The indemnification obligations set forth in this Clause 15.1 shall not apply to the extent that any such Losses arising from such Third Party Claim arose or resulted from the events specified in Clause 15.2(a)-(d).

15.2 Except as provided in Clause 15.1 above, Ascendis shall indemnify, defend and hold harmless the Licensee, its Affiliates, and their respective directors, officers, employees and agents (each a "Licensee Indemnitee") from and against all Losses arising out of or resulting from any Third Party Claims to the extent such Losses result from or arise out of: (a) the activities performed by Ascendis, its Affiliates, and Sublicensees in connection with the exercise of its rights or obligations under this Agreement, including the exploitation of the Licensed Product(s) outside of the Territory; (b) breach by Ascendis of the representations and warranties provided in Clause 14; (c) gross negligence, recklessness or wilful misconduct by Ascendis, its Affiliates, and Sublicensees; or (d) violation of Applicable Law by Ascendis, its Affiliates, and Sublicensees. The indemnification obligations set forth in this Clause 15.2 shall not apply to the extent that any such Third Party Claim arose or resulted from the events specified in Clause 15.1(a)-(d).

15.3 In the event that an Ascendis Indemnitee or a Licensee Indemnitee, as applicable (hereinafter an "Indemnified Party") seeks indemnification under this Clause 15, such Indemnified Party shall: (i) give prompt notice to the indemnifying Party of any such Third Party Claim; (ii) permit the indemnifying Party to assume direction and control of the defence of such Third Party Claim (including decisions regarding its settlement or other disposition, which may be made in the indemnifying Party's sole discretion except as otherwise provided herein); (iii) assist the indemnifying Party at the indemnifying Party's expense in defending such Third Party Claim; and (iv) not compromise or settle such Third Party Claim without the indemnifying Party's prior written consent, which shall not be unreasonably withheld or delayed. The failure to deliver written notice to the indemnifying Party within a reasonable time after the commencement of any such Third Party Claim, to the extent prejudicial to its ability to defend such Third Party Claim, shall relieve the indemnifying Party of any obligation to the Indemnified Party under this Clause 15. The Indemnified Party may participate in the defence of such Third Party Claim through counsel of its choice, but the reasonable cost of such counsel shall be borne solely by the Indemnified Party. It is understood that only Ascendis or the Licensee may claim indemnity under this Clause 15 (on its own behalf or on behalf of its Indemnified Parties), and other Indemnified Parties may not directly claim indemnity hereunder. No compromise or settlement of any Third Party Claim may be effected by the indemnifying Party without the Indemnified Party's prior written consent (which consent shall not be unreasonably withheld or delayed), unless: (a) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnified Party; (b) the sole relief provided is monetary damages that are paid in full by the indemnifying Party; and (c) the Indemnified Party's rights under this Agreement are not adversely affected. The Indemnified Party shall have no right to settle any such Third Party Claim without the prior written consent of the indemnifying Party (and any such settlement without the prior written consent of the indemnifying Party shall relieve the indemnifying Party of its obligations under this Clause 15), unless: (x) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnifying Party; (y) the sole relief provided is monetary damages that are paid in full by the Indemnified Party; and (z) the indemnifying Party's rights under this Agreement are not adversely affected.

16. **Limitation of Liability**

16.1 Subject to Clause 16.2, neither of the Parties nor any of their Affiliates shall be liable to each other under any contract, negligence, strict liability or other legal or equitable theory for indirect, incidental, special, punitive, exemplary or consequential damages arising out of or resulting from this Agreement. The foregoing shall not limit:

(A) the obligations of either Party from and against Third Party claims under Clauses 15.1 or 15.2 to the extent that such Third Party has been awarded such damages;

(B) the liability of a Party as a result of its breach of Clause 10; or

(C) the liability of either Party under Clause 2.3.

16.2 Neither Party limits or excludes its liability for fraud, fraudulent concealment or fraudulent misrepresentation, nor for death or personal injury arising from its negligence.

16.3 Ascendis and Ascendis Pharma A/S shall be jointly and severally liable for any liabilities incurred by or on behalf of Ascendis under this Agreement.

17. **Term and Survival**

17.1 This Agreement shall commence with effect from the Effective Date and shall continue for so long as a Valid Claim of an Ascendis Patent exists in the Territory, unless terminated earlier pursuant to Clause 18.

17.2 On the expiration or other termination of this Agreement each Party shall continue to be bound by Clauses 2.2 (solely in the event of expiration, or as it may be modified by Clause 19.3 in specified events of termination), 8 (Records and Auditing), 9.2 (Pharmacovigilance), 10 (Confidentiality), 11.1 and 11.2 (Intellectual Property), 15 (Indemnification), 16 (Limitation of Liability), 17 (Term and Survival), 19 (Effect of Termination), 20 (Dispute Resolution) and 21 (Miscellaneous).

18. **Termination**

18.1 **Licensee termination for convenience**

The Licensee may terminate this Agreement at any time for any reason by giving ninety (90) days' prior written notice to Ascendis.

18.2 **Right to Terminate for Material Breach**

(a) In the event that Ascendis commits a material breach of any of the terms of this Agreement on its part to be performed or observed, Licensee shall have the right to terminate this Agreement, in whole or in part, by giving sixty (60) days' written notice to Ascendis; provided, however, that in the case of a material breach capable of being remedied, if Ascendis shall remedy such material breach within sixty (60) days after the notice has been given, then the notice shall not be effective and the Agreement shall not terminate.

(b) In the event that Licensee commits a material breach of any of the material obligations under Section 2.3, 7.1, 7.2 or 10 and such material breach causes material loss by Ascendis that exceeds [***] dollars ($[***]), Ascendis shall have the right to terminate this Agreement, in whole or in part, by giving ninety (90) days' written notice to Licensee; provided, however, that if Licensee shall remedy such material breach or reduce such loss below [***] dollars ($[***]) within ninety (90) days after the notice has been given, then the notice shall not be effective and the Agreement shall not terminate.

18.3 **Right to Terminate for Bankruptcy**

(A) **Right to terminate**

A Party (the "Non-Bankrupt Party") may, to the extent legally permissible and in addition to any other remedies available to it by law or in equity, terminate this Agreement, as a whole by notice to the other Party (the "Bankrupt Party"), in the event the Bankrupt Party has become bankrupt, has made an assignment for the benefit of its creditors or there has been appointed a trustee or receiver of the Bankrupt Party for all or a substantial part of its property or any case or proceeding shall have been commenced or other action taken by or against the Bankrupt Party in bankruptcy or seeking reorganisation, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganisation or other similar act or law of any jurisdiction now or hereafter in effect and any such event shall have continued for sixty (60) days undismissed, unbonded and undischarged.

(B) **Retention of rights upon Bankruptcy**

In the event of a bankruptcy of the Bankrupt Party, the rights and licences granted under or pursuant to this Agreement by the Bankrupt Party to the Non-Bankrupt Party are, and shall otherwise be deemed to be, for purposes of paragraph 365(n) of the United States Bankruptcy Code, licences of rights to "intellectual property" as defined under paragraph 101(35A) of the United States Bankruptcy Code. The Parties agree that the Non-Bankrupt Party, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code. The Parties further agree that in the event of the commencement of a bankruptcy proceeding by or against the Bankrupt Party, including under the United States Bankruptcy Code, the Non-Bankrupt Party shall, to the extent legally permissible, be entitled to complete access to any such intellectual property of the Bankrupt Party that pertains to the rights granted in the licenses under this Agreement and embodiments of such intellectual property.

18.4 **Ascendis termination for Change of Control.** Ascendis may terminate this Agreement as a whole, effective immediately upon written notice to Licensee, in the event of a Change of Control in favour of a Competitor.

18.5 **Ascendis termination for Patent challenge.**

(A) Without limiting Clause 18.5(B), [***], Ascendis may terminate this Agreement as a whole effective upon thirty (30)-day written notice to the Licensee, if the Licensee or its Affiliates challenges [***] in a court the validity, [***] of any Ascendis Patent and such challenge is not withdrawn within such thirty (30)-day period, unless Ascendis or its Affiliates or any of its licensees has [***].

(B) At any time during the Term, Ascendis may terminate this Agreement as a whole effective upon thirty (30)-day written notice to the Licensee, if the Licensee or its Affiliates challenges [***] in a court the validity, [***] of any (i) Ascendis Patent [***] or (ii) any Ascendis Patent [***], and in either case of (i) or (ii), such challenge is not withdrawn within such thirty (30)-day period, unless Ascendis or its Affiliates or any of its licensees has [***].

19. **Effect of Termination**

19.1 The termination of this Agreement shall be without prejudice to:

(A) the obligation of the Licensee to pay to Ascendis all sums accrued, due and payable under Clause 7 as of the effective date of termination; and

(B) any right of, or remedy available to, either Party against the other in respect of any action or omission hereunder prior to such termination.

19.2 **Termination by the Licensee**

(A) **For Convenience**

In the event of termination of this Agreement in whole or in part by the Licensee pursuant to Clause 18.1:

(1) the licences granted to Ascendis and its Affiliates under Clause 2.2 shall [***], except that [***], and [***];

(2) Licensee shall transfer, or cause to be transferred, all [***] existing as of the effective date of such termination to Ascendis or its designee, [***], and [***];

(3) the licences granted to the Licensee under Clause 2.1 shall terminate as of the effective date of such termination;

(4) [***]; and

(5) obligations under Clause 2.3 shall cease for both Parties and their Affiliates.

(B) **For Ascendis' breach or bankruptcy**

In the event of termination of this Agreement in whole by the Licensee pursuant to Clauses 0 or 18.3(A), subject to Clause 19.5:

(1) the licence granted to the Licensee under Clause 2.1 (and all sublicenses granted thereunder) shall survive (along with all obligations associated therewith) in respect of any Ascendis Patents, Ascendis Technical Information, Ascendis Program IP and Ascendis' and its Affiliates' interest in Joint Program IP that exist as of the effective date of such termination;

(2) the licence granted to Ascendis and its Affiliates under Clause 2.2 shall survive (along with all obligations associated therewith), in respect of the Licensee's and its Affiliates' interest in any Joint Program IP and Licensee Program IP that exist as of the effective date of such termination;

(3) [***];

(4) if the effective date of such termination is prior to the [***] anniversary of the Effective Date, unless otherwise agreed to by the Licensee, Ascendis' obligations under Clause 5.1 shall survive until the [***] anniversary of the Effective Date; and

(5) Ascendis' and its Affiliates' obligations under Clause 2.3(A) shall survive until the [***] anniversary of the effective date of such termination.

19.3 **Termination by Ascendis**

In the event of termination of this Agreement in whole or in part by Ascendis pursuant to Clauses 18.2, 18.3, 18.4 or 18.5, subject to Clause 19.4:

(A) the licence granted to Ascendis and its Affiliates under Clause 2.2 shall [***], except that [***], and Ascendis [***];

(B) Licensee shall transfer, or cause to be transferred, [***] existing as of the effective date of such termination to Ascendis or its designee, [***], and Ascendis shall [***];

(C) [***];

(D) obligations under Clause 2.3 shall cease for both Parties and their Affiliates; and

(E) the licence granted to the Licensee under Clause 2.1 shall terminate as of the effective date of the termination.

19.4 **Inventory at termination**

In the event this Agreement is terminated for any reason, the Licensee shall have the right to sell or otherwise dispose of Licensed Product then in its stock for up to [***] ([***]) months following the termination of this Agreement.

19.5 **Continuation of sub-licences**

Upon termination of this Agreement, any existing, permitted sub-licence granted by a Party under this Agreement shall continue in full force and effect, provided that the permitted Sub-Licensee did not cause the breach that gave rise to a termination under Clause 18.2 and agrees to be bound by all the terms and conditions of this Agreement that are applicable to such permitted Sub-Licensee, including, without limitation, rendering directly to the licensing Party all payments and other obligations due to the licensing Party related to such sub-licence.

19.6 **Return of Confidential Information**

Following any expiration or termination of this Agreement, the Party that has Confidential Information of the other Party shall return to the other Party (or destroy at such Party's written request) all such Confidential Information in its possession as of the effective date of expiration or termination (with the exception of one copy of such Confidential Information, which may be retained by the legal department of the Party that received such Confidential Information to confirm compliance with the non-use and non-disclosure provisions of this Agreement, and any Confidential Information of the other Party contained in its laboratory notebooks or databases.

20. **Dispute Resolution**

20.1 **Internal resolution**

(A) Any dispute, controversy or claim related to matters within the powers and authority of the JDC shall be resolved by the Parties in accordance with procedures set forth in Clause 4.6.

(B) Except as otherwise expressly provided herein, including in Clause 20.1(A) above, in the event of any controversy, claim or other dispute arising out of or relating to compliance with this Agreement, or the validity, breach, termination or interpretation of this Agreement, such dispute shall be first referred to the Executives for resolution, prior to proceeding under the following provisions of Clause 20.2. A dispute shall be referred to the Executives upon one Party providing the other Party with written notice that such dispute exists, and the Executives shall attempt to resolve such dispute through good faith discussions. In the event that the Executives cannot resolve such dispute within [***] ([***]) days of such other Party's receipt of such written notice, either Party may initiate the dispute resolution procedures set forth in Clause 20.2. The Parties agree that any discussions between such Executives, or their designees, regarding such dispute shall be the Confidential Information of both Parties and do not constitute settlement discussions, unless the Parties agree otherwise in writing.

20.2 **Arbitration**

Except as otherwise expressly provided in this Agreement, including but not limited to Clause 20.3, the Parties agree that any dispute not resolved internally by the Parties pursuant to Clause 20.1(B), shall be resolved through binding arbitration conducted under the auspices of the [***] (for purposes of this Clause 20.2, the "Rules"), except as modified in this Agreement, applying the substantive law specified in Clause 21.12 (Governing law). A Party may initiate arbitration by written notice to the other Party of its intention to arbitrate, and such demand notice shall specify in reasonable detail the nature of the dispute. Each Party shall select one (1) arbitrator, and the two (2) arbitrators so selected shall choose a third arbitrator. All three (3) arbitrators shall serve as neutrals and have at least [***] ([***]) years of: (a) dispute resolution experience (including judicial experience); and/or (b) legal or business experience in the biotech or pharmaceutical industry. In any event, at least one (1) arbitrator shall satisfy the foregoing experience requirement under Clause 20.2(b). Notwithstanding anything to the contrary in this Clause 20.2, in the event of a dispute regarding the Prosecution and Maintenance activities described in Clause 12 at least one (1) arbitrator shall have expertise in patent law. If a Party fails to nominate its arbitrator, or if the Parties' arbitrators cannot agree on the third arbitrator, the necessary appointments shall be made in accordance with the Rules. Once appointed by a Party, such Party shall have no *ex parte* communication with its appointed arbitrator. The arbitration proceedings shall be conducted in [***]. The arbitration proceedings and all pleadings and written evidence shall be in the English language. Any written evidence originally in another language shall be submitted in English translation accompanied by the original or a true copy thereof. Each Party agrees to use commercially reasonable efforts to make all of its current employees available, if reasonably needed, and agrees that the arbitrators may deem any party as "necessary." The arbitrators shall be instructed and required to render a written, binding, non-appealable resolution and award on each issue that clearly states the basis upon which such resolution and award is made. The written resolution and award shall be delivered to the Parties as expeditiously as possible, but in no event more than [***] ([***]) days after conclusion of the hearing, unless otherwise agreed by the Parties. Judgment upon such award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such an award and order for enforcement. [***] The Parties may apply to any court of competent jurisdiction for a temporary restraining order, preliminary injunction or other interim or conservatory relief, as necessary, without breaching these arbitration provisions and without abridging the powers of the arbitrators. At the request of either Party, the arbitrators shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings. The arbitrators shall have the power to decide all questions of arbitrability. The Parties agree that: (i) they shall share equally the fees and expenses of the arbitrators; and (ii) each Party shall bear its own attorneys' fees and associated costs and expenses.

20.3 **Patent validity**

Notwithstanding the other provisions of this Clause 20, any dispute that involves the validity, infringement or claim interpretation of a Patent that is issued: (a) in the United States shall be subject to actions before the United States Patent and Trademark Office and/or submitted exclusively to the federal court located in the jurisdiction of the district where any of the defendants resides; and (b) in any other country shall be brought before an appropriate regulatory or administrative body or court in that country, and the Parties hereby consent to the jurisdiction and venue of such courts and bodies. For the sake of clarity, such Patent disputes shall not be subject to the provisions of Clause 20.2. Nothing in this Agreement shall be construed to prevent the Licensee from disputing or challenging the validity of a Third Party's Patent.

21. **Miscellaneous**

21.1 **General assurances**

At any time after the date hereof each of the Parties shall, at the request and cost of the other Party, execute or procure the execution of such documents and perform or procure the performance of such acts as the other Party may reasonably require for the purpose of giving to the other Party the full benefit of all the provisions of this Agreement, subject to any express restrictions in this Agreement on the extent of either Party's obligations under this Agreement. This includes in particular (without prejudice to the generality of the foregoing) entry into forms of licence or other instruments confirming such rights for registration with appropriate Intellectual Property Offices (including in the form set out in Schedule 4), Regulatory Authorities and other authorities in the Territory.

21.2 **Unenforceability and severability**

If any of the provisions of this Agreement are held to be void or unenforceable, then such void or unenforceable provisions shall be replaced by valid and enforceable provisions that will achieve as far as possible the economic business intentions of the Parties. However, the remainder of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e. the Parties would presumably have concluded this Agreement without the unenforceable provisions.

21.3 **Assignments**

Neither this Agreement nor any of the rights and obligations created herein is assignable or transferable by either Party without the prior written consent of the other, such consent not to be unreasonably withheld or delayed.

Notwithstanding the preceding sentence, each Party is entitled to assign this Agreement and any rights created herein to, subject to the assumption of the obligations herein by, any Affiliate of such Party or any purchaser of the whole or a substantial part of the business of such Party. For the avoidance of doubt, the Parties agree that the Ascendis Platform Technology constitutes a substantial part of the business of Ascendis.

21.4 **Rights cumulative and other matters**

(A) The rights, powers, privileges and remedies provided in this Agreement are cumulative and are not exclusive of any rights, powers, privileges or remedies provided by law or otherwise.

(B) No failure to exercise nor any delay in exercising by any Party to this Agreement of any right, power, privilege or remedy under this Agreement shall impair or operate as a waiver thereof in whole or in part.

(C) No single or partial exercise of any right, power privilege or remedy under this Agreement shall prevent any further or other exercise thereof or the exercise of any other right, powers, privilege or remedy.

21.5 **Costs of preparation**

The Parties hereto shall pay their own respective legal costs incurred in the preparation of this Agreement.

21.6 **Entire Agreement and variation**

(A) This Agreement, together with any documents referred to in it, constitutes the whole agreement between the Parties relating to its subject matter and supersedes and extinguishes any prior drafts, agreements, undertakings, representations, warranties and arrangements of any nature, whether in writing or oral, relating to such subject matter. All information related to the subject matter of this Agreement previously exchanged shall be protected under Clause 10 of this Agreement as if disclosed under this Agreement.

(B) Each Party acknowledges that it has not been induced to enter into this Agreement by any representation or warranty other than those contained in this Agreement and, having negotiated and freely entered into this Agreement, agrees that it shall have no remedy in respect of any other such representation or warranty except in the case of fraud.

(C) No variation of this Agreement shall be effective unless made in writing and signed by each of the Parties.

21.7 **Notices and invoices**

(A) Any notice (which term shall in this Clause 21.7 include any communication) required to be given under this Agreement or in connection with the matters contemplated by it shall, except where otherwise specifically provided, be in writing in the English language.

(B) Any such notice shall be addressed as provided in Clause 21.7(C) and may be:

(1) personally delivered, in which case it shall be deemed to have been given upon delivery at the relevant address if it is delivered not later than 17.00 hours on a Business Day, or, if it is delivered later than 17.00 hours on a Business Day or at any time on a day which is not a Business Day, at 08.00 hours on the next Business Day;

(2) sent by pre-paid registered airmail, or by air courier in which case it shall be deemed to have been given seven (7) Business Days after the date of posting in the case of registered airmail or two (2) Business Days after delivery to the courier, in the case of air courier;

(3) sent by electronic mail, in which case it shall be deemed to have been given when sent from the electronic mail exchange, provided that any notice sent by electronic mail after 17.00 hours on any Business Day or at any time on a day which is not a Business Day shall be deemed to have been given at 08.00 on the next Business Day.

(C) The addresses and other details of the Parties referred to in this Clause 21.7(C) are, subject to Clause 21.7(D):

Ascendis' address:

Ascendis Pharma Growth Disorders A/S
Tuborg Boulevard 5
DK-2900 Hellerup
Denmark

Email: [***]
Attention: [***]

VISEN Pharmaceuticals's address:

VISEN Pharmaceuticals
P.O. Box 472
2nd Floor, Harbour Place
103 South Church Street
George Town, Grand Cayman KY1-1106
Cayman Islands

Email: [***]
Attention: [***]

(D) Either Party to this Agreement may notify the other Party of any change to the address or any of the other details specified in Clause 21.7, provided that such notification shall only be effective on the date specified in such notice or five (5) Business Days after the notice is given, whichever is later.

(E) **Invoices**

All invoices that are required or permitted under this Agreement shall be in writing and sent by Ascendis to the Licensee at the address provided under Clause 21.7(C).

21.8 **Force Majeure**

Neither Party to this Agreement shall be deemed to be in breach of this Agreement or otherwise liable to the other as a result of any delay or failure in the performance of its obligations under this Agreement if and to the extent that such delay or failure is caused by Force Majeure, and the time for performance of the relevant obligation(s) shall be extended accordingly. The Party concerned shall promptly notify the other Party of the nature and effect of such event and both Parties shall, where the same is practicable, use Diligent Efforts to minimise such effect and to comply with the respective obligations herein contained as nearly as may be in their original form, provided that if the Force Majeure event continues for a period of ninety (90) days or more following notification, the Party not affected by the event may terminate this Agreement by giving not less than thirty (30) days prior notice to the other Party.

21.9 **Relationship of the Parties**

(A) Nothing in this Agreement shall constitute, or be deemed to constitute, a partnership between the Parties nor, except as expressly provided, shall it constitute, or be deemed to constitute, any Party the agent of any other Party for any purpose.

(B) Subject to any express provisions to the contrary in this Agreement, neither Party shall have any right or authority to and shall not do any act, enter into any contract, make any representation, give any warranty, incur any liability, assume any obligation, whether express or implied, of any kind on behalf of the other Party or bind the other Party in any way.

21.10 **Counterparts**

This Agreement may be executed in any number of counterparts, which shall together constitute one Agreement. Any Party may enter into this Agreement by signing any such counterpart.

21.11 **Third Party rights**

No person who is not a party to this Agreement shall have any right to enforce any term of this Agreement.

21.12 **Governing law**

This Agreement shall be governed by and construed in accordance with the laws of the state of Delaware, USA, without reference to its conflict of laws principles, and shall not be governed by the United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention).

[Signature page follows]

AS WITNESS the Parties hereof have executed this Agreement the day and year first before written.

Signed by	) /s/ Michael Wolff Jensen
for and on behalf of	) Michael Wolff Jensen, Chairman
ASCENDIS PHARMA	) /s/ Jan Mikkelsen
GROWTH DISORDERS A/S	) Jan Mikkelsen, CEO
Signed by	) /s/ Shan Fu
for and on behalf of	) Shan Fu
VISEN PHARMACEUTICALS	) Director

SCHEDULE 1 : ASCENDIS PATENTS

[***]

SCHEDULE 2: ASCENDIS TECHNICAL INFORMATION

1.1 [***]

SCHEDULE 3: EXCLUDED INDICATIONS

[***]

SCHEDULE 4 : SHORT FORM PATENT LICENCE

THIS AGREEMENT is made the [ ] day of [ ]

BETWEEN:

(1) **ASCENDIS PHARMA GROWTH DISORDERS A/S**, ("Ascendis"), a company registered in Denmark with its registered office at Tuborg Boulevard 5, DK-2900 Hellerup, Denmark; and

(2) **VISEN PHARMACEUTICALS**, a company registered under the laws of Cayman Islands with its registered address at P.O. Box 472, 2nd Floor, Harbour Place, 103 South Church Street, George Town, Grand Cayman KY1-1106, Cayman Islands.

Ascendis and the Licensee are each a "Party", and together the "Parties", to this agreement.

Ascendis hereby grants to the Licensee an exclusive licence for exploitation of the patent(s) set out in the Appendix below worldwide for the treatment and/or prevention of any disease, condition or disorder of the eye and adnexa, defined according to WHO ICD (but non-exclusive for Diabetic Retinopathy), subject to and terminable in accordance with the terms and conditions of an agreement between the Parties hereto dated [ ].

Appendix

[insert details of relevant patents/patent applications]

AS WITNESS the Parties have executed this agreement the day and year first above written.

Signed by	)
for and on behalf of	)
ASCENDIS PHARMA	)
GROWTH DISORDERS A/S	)
Signed by	)
for and on behalf of	)
VISEN PHARMACEUTICALS	)

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

EXECUTION VERSION
CONFIDENTIAL

Exclusive Licence Agreement

between

Ascendis Pharma Endocrinology Division A/S

as the Licensor or Ascendis on the one hand

and

VISEN PHARMACEUTICALS

as the Licensee on the other hand

CONTENTS

THIS EXCLUSIVE LICENCE AGREEMENT (the "Agreement") is dated November 7, 2018 and made

BETWEEN:

(1) **ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S**, ("Licensor" or "Ascendis"), a company registered in Denmark with its registered office at Tuborg Boulevard 5, DK-2900 Hellerup, Denmark;

(2) **VISEN PHARMACEUTICALS**, ("Licensee"), a company established under the laws of the Cayman Islands with its registered address at P.O. Box 472, 2nd Floor, Harbour Place, 103 South Church Street, George Town, Grand Cayman KY1-1106, Cayman Islands.

Ascendis and the Licensee are each a "Party", and together the "Parties", to this Agreement.

Background:

(A) Ascendis and its Affiliates Control proprietary rights, titles and interests in patents and technical information relating to Licensed Products (as defined below) within the area of growth disorders.

(B) The Licensee wishes to develop and to commercialise such Licensed Products in the Field in the Territory (such terms defined below), and Ascendis wishes to grant the Licensee an exclusive licence under certain patents, technical information and other intellectual property to develop and commercialise such Licensed Products in the Field in the Territory, on the terms and conditions of this Agreement.

THE PARTIES AGREE THAT:

1. **Interpretation**

1.1 **Definitions**

"Accounting Standard" means, with respect to the Licensee, either: (a) International Financial Reporting Standards ("IFRS"); or (b) United States generally accepted accounting principles ("GAAP"), in either case, which standards or principles (as applicable) are currently used at the applicable time, and as consistently applied, by the Licensee.

"Affiliate" means any business Entity which from time-to-time controls, is controlled by or is under common control with a Party to this Agreement, in each case only for so long as such control exists. As used in this definition, "control" of an Entity means the beneficial ownership (either directly or indirectly) of more than fifty percent (50%) of the total voting power of the shares or securities then outstanding normally entitled to vote in elections of the board of directors or other managing authority of such Entity. For the avoidance of doubt, neither Licensee nor any of its subsidiaries shall be considered as an Affiliate of Ascendis and an Affiliate of Ascendis shall not be considered as an Affiliate of either Licensee or its subsidiaries for the purposes of this Agreement.

"Applicable Laws" means all laws, statutes, codes, ordinances, rules and regulations that have been enacted (including without limitation by a Regulatory Authority) in any jurisdiction in the Territory and which are in force as of the Effective Date or come into force during the term of this Agreement and that are applicable to the research, development, Manufacture, or commercialization of Licensed Product or the activities of the Parties under this Agreement, including, without limitation: (a) applicable regulations and guidelines of the NMPA and other Regulatory Authorities and the ICH guidelines; (b) applicable Good Clinical Practices, Good Laboratory Practices and Good Manufacturing Practices promulgated by the NMPA and other Regulatory Authorities or the ICH; and (c) all applicable industry and trade standards, including the applicable standards of the ISO with, at a minimum, the ISO 9001/9002 quality standards.

"Ascendis FTE Costs" means, for all activities performed by Ascendis or its Affiliates in accordance with the Research and Technical Development Plan or as otherwise directed in writing by the Licensee and agreed to by Ascendis or its Affiliates, the product of: (a) the number of FTEs used by Ascendis or its Affiliates for such activities as set forth in a Research and Technical Development Plan or other written document approved by the Licensee; and (b) the Ascendis FTE Rate. For the avoidance of doubt, the costs of approved service providers fulfilling the obligations of Ascendis or its Affiliates in performing such activities are covered separately under subsection (A) of the "Research and Technical Development Plan Expenses" definition, and are not a part of the Ascendis FTE Costs.

"Ascendis FTE Rate" means (a) if, at the time the applicable Ascendis FTE Costs are incurred, Ascendis owns [***] percent ([***]%) or more of all outstanding preferred shares of Licensee, [***] Euros (€ [***]) per FTE, and (b) if, at the time the applicable Ascendis FTE Costs are incurred, Ascendis owns less than [***] percent ([***]%) of outstanding preferred shares of Licensee, [***] Euros (€ [***]) per FTE; provided in each case of (a) and (b), such amount is fully burdened and includes without limitation, for each FTE, [***], utilities, [***], and a pro rata allocation of general and administrative expenses.

"Ascendis Program IP" means: any Program IP conceived or generated solely by employees, agents or service providers of Ascendis or its Affiliates.

"Ascendis Indemnitee" has the meaning ascribed to it in Clause 15.1.

"Ascendis Patents" means: (a) the patents and patent applications listed in Schedule 1 as of the Effective Date and any conversion, continuation, continuation-in-part, division, provisional or substitution thereof, and any patents issuing thereon, any reissues, re-examinations, confirmations or extensions of such patents (including supplementary protection certificates) and any foreign counterparts of such patent applications and patents in any country in the Territory; and (b) any and all other Patents that are Controlled by Ascendis or its Affiliates as of the Effective Date or at any time thereafter during the term of this Agreement (including without limitation Patents within the Ascendis Program IP or Joint Program IP) that are necessary or useful to make, have made, use, sell, offer for sale or import a Licensed Product.

"Ascendis Technical Information" means: (a) the Technical Information listed in Schedule 2 as of the Effective Date; and (b) any and all other Technical Information that is Controlled by Ascendis or its Affiliates, as of the Effective Date or at any time thereafter during the term of this Agreement (including without limitation Technical Information within the Ascendis Program IP or Joint Program IP), that is necessary or useful to make, have made, use, sell, offer for sale or import a Licensed Product.

"Ascendis Platform Technology" means, as of the Effective Date or at any time thereafter during the term of this Agreement, Ascendis' proprietary chemistry, materials and methodologies for [***] a substrate of interest (e.g., [***] to various carriers (including [***]) *via* a TransCon Linker, [***].

"Auto Injector" means any device developed by Ascendis for the purpose of administering TransCon hGH.

"Bankrupt Party" has the meaning ascribed to it in Clause 18.3(A).

"Business Day" means a day (other than a Saturday or Sunday) on which banks are open for ordinary face to face banking business in Copenhagen (Denmark), Cayman, China, and San Francisco (California, USA).

"Change of Control" means the occurrence of any of the following events: (a) any Competitor takes control (as the term "control" is defined in the definition of "Affiliate") of Licensee; or (b) Licensee: (i) consolidates with, or merges with or into, a Competitor; or (ii) transfers all or substantially all of its assets to any Competitor.

"Competitor" means (a) a Third Party that [***] commercializing (i.e., as the party having the proprietary rights to and booking sales for, but not as a distributor or wholesaler of) a [***] in [***] as of the date of a Change of Control; and (b) [***] as of the date of a Change of Control.

"Confidential Information" means confidential Technical Information (of whatever kind and in whatever form or medium, including copies thereof): (a) disclosed by or on behalf of a Party in connection with this Agreement, whether prior to or during the term of this Agreement and whether disclosed orally, electronically, by observation or in writing; and/or (b) created by, or on behalf of, either Party, or created jointly by the Parties, in the course of this Agreement. "Confidential Information" includes confidential Technical Information regarding such Party's research, development plans, clinical trial designs, preclinical and clinical data, technology, products, business information or objectives and other information of the type that is customarily considered to be confidential information by Parties engaged in activities that are substantially similar to the activities being engaged in by the Parties pursuant to this Agreement. The following shall be deemed the Confidential Information of the Licensee: any and all financial or product pipeline information related to the Licensee provided to Ascendis (whether provided by the Licensee itself or through a Third Party), as well as Licensee Program IP, and the Research and Technical Development Plans. The following shall be deemed the Confidential Information of Ascendis: Ascendis Platform Technology, Ascendis Technical Information, Ascendis Program IP and Ascendis Patents. The following shall be deemed the Confidential Information of both Parties: the terms and conditions of this Agreement.

"Control" or "Controlled" means, with respect to an item of information or Intellectual Property, that a Party has the right, power and legal authority, whether arising by ownership, licence or other authorisation, to disclose, and/or to grant and authorise licences or sub-licences under, such items as required under the terms of this Agreement, without violating the terms of any written agreement with any Third Party under which such Party or its Affiliates first acquired such rights to such item of information or Intellectual Property.

"Diligent Efforts" means with respect to a Party's research, development, and commercialisation of Licensed Products, the level of efforts and resources such Party would typically exert in similar circumstances pursuing the development and commercialisation of a similar product with similar market potential taking into account the stage of development or commercialisation, market potential and market size, the product life cycle, the risk of development or commercialisation of the Licensed Product, the cost effectiveness of efforts or resources, the competitiveness of alternative products that are or are expected to be in the marketplace, the scope and duration of patent rights or other proprietary rights related to the Licensed Product, and the profitability of the Licensed Product [***]. The efforts and resources of each Party's respective Affiliates and Sub-Licensees shall count towards that Party's own Diligent Efforts. Notwithstanding the foregoing, the exercise of diligence by the Licensee shall be determined by judging the Licensee's commercially reasonable efforts taken as a whole[***].

"Effective Date" means the date of this Agreement.

"Endocrinology Disorders" means [***]

"Endocrinology Product" means a product consisting of a substrate of interest (e.g., [***] to a carrier of interest (including [***]) via a TransCon Linker for the treatment of Endocrinology Disorders; provided, that [***]

"Entity" means, and includes, any person, firm or company or group of persons or unincorporated body.

"Excluded Indications" means the indications specified in Schedule 3.

"Executives" means the Chief Executive Officer at the Licensee and the Chief Executive Officer at Ascendis.

"FDA" means the US Food and Drug Administration or any successor agency with comparable responsibilities.

"Field" means the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the Excluded Indications.

"Force Majeure" means any circumstances not within the reasonable control of the Party concerned including, without limitation: (a) any strike, lockout or other industrial action, or any shortage of or difficulty in obtaining labour, fuel, raw materials or components; (b) any destruction, temporary or permanent breakdown, malfunction or damage of or to any premises, plant, equipment (including computer systems) or materials; (c) any breach of contract, default or insolvency by or of any Third Party, other than an Affiliate of the Party affected by the force majeure, or an employee or officer of that Party or Affiliate; (d) any action taken by a governmental or public authority imposing an embargo, export or import restriction, rationing, quota or other restriction or prohibition; (e) any civil commotion or disorder, riot, invasion, war, threat of or preparation for war; or (f) any accident, fire, or explosion, (other than in each case, one caused by a breach of contract by or assistance of the Party concerned) storm, flood, earthquake, subsidence, epidemic or other natural physical disaster. Notwithstanding the foregoing, lack of funds, manpower or equipment, interruption or failure of utility service and the fault or misconduct by any personnel engaged by a Party shall not be an event of Force Majeure.

"FTE" means a full time equivalent person year of work (consisting of [***]), prorated on a daily or hourly basis as necessary.

"Good Clinical Practice" means the applicable principles and guidelines for good clinical practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation those set out in the Harmonised Tripartite Guideline for Good Clinical Practice as finalised by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"Good Distribution Practice" means the applicable principles and guidelines for good distribution practice of drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation those set out in Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use, based on Article 84 and Article 85b(3) of Directive 2001/83/EC.

"Good Laboratory Practice" means the applicable principles and guidelines for good laboratory practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation those set out in the OECD Principles of Good Laboratory Practice published by the Organisation for Economic Co-Operation and Development.

"Good Manufacturing Practice" means all applicable principles and guidelines for good manufacturing practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation as specified in the applicable provisions of (i) European Directive 2003/94/EC and further guidance as published by the European Commission in Volume IV of "The rules governing medicinal products in the European Community" and (ii) Title 21 Parts 210 and 211 of the US Code of Federal Regulations (21 CFR, parts 210 and 211).

"ICH" means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"Indemnified Party" has the meaning ascribed to it in Clause 15.3.

"Intellectual Property" means registered or unregistered trademarks, Patents, registered designs, unregistered design rights, business, company, domain or product names, service marks, copyright, know-how, Confidential Information, database rights, any rights in clinical study results, applications for and the right to apply for any of the foregoing, and any similar or analogous rights anywhere in the Territory.

"Intellectual Property Office" means the official local patent, trade mark or other Intellectual Property registry in each part of the Territory responsible for granting, maintaining records of, Patents, trademarks or other Intellectual Property and any instruments made in respect thereof.

"ISO" means the International Organization for Standardization.

"Joint Development Committee" or "JDC" means the joint development committee established under Clause 4.6.

"Joint Program IP" means any Program IP conceived or generated during the course of, and in connection with, this Agreement by employees, agents or service providers of both Ascendis and the Licensee or their respective Affiliates or Sub-Licensees.

"Licensed Product" means a product consisting of human growth hormone (hGH) [***] to a carrier [***] by a TransCon Linker and which is developed utilizing the Ascendis Platform Technology, regardless of its finished form, formulation or dosage, alone (the foregoing alone, "TransCon hGH") or also including the Auto Injector.

"Licensed Product Patents" means all Ascendis Patents that claim [***] a Licensed Product in the form as which is concurrently being developed or commercialised, as applicable, by or on behalf of Ascendis or its Affiliates outside of the Territory.

"Licensee Program IP" means: any Program IP conceived or generated solely by employees, agents or service providers of the Licensee or its Affiliates.

"Licensee Indemnitee" has the meaning ascribed to it in Clause 15.2.

"Long-Acting Product" is a product that is intended to be administered to a subject once a week or less frequently than once a week.

"Loss" or "Losses" means any and all losses, liabilities, damages, fines, penalties, costs or expense (including reasonable attorneys' fees and other expenses of litigation).

"Manufacture" or "Manufacturing" means any manufacturing activity of any Licensed Product, or any ingredient thereof, including manufacturing for pre-clinical or clinical use, or commercial sale, testing, handling, packaging and storage, ongoing stability tests and regulatory activities related to any of the foregoing.

"NMPA" means the National Medical Product Administrations of the People's Republic of China, or any successor agency with comparable responsibilities.

"Non-Bankrupt Party" has the meaning ascribed to it in Clause 18.3(A).

"Patents" means any and all: (a) issued patents, including inventor's certificates; (b) patent applications, including any conversion, continuation, continuation-in-part, division, provisional or substitution thereof, and any patents issuing thereon; (c) any reissues, re-examinations, confirmations or extensions of such patents (including supplementary protection certificates); and (d) any foreign counterparts of such patent applications and patents in any country in the Territory.

"Program IP" means any data, results (including all clinical data), improvements and inventions generated by or on behalf of Ascendis or Licensee, or the Parties jointly, in connection with the research, development, Manufacturing, or commercialization activities conducted with respect to the Licensed Product under this Agreement, and all Intellectual Property therein.

"Quarterly Period" means each period of three months commencing on 01 January, 01 April, 01 July and 01 October in a given calendar year.

"Regulatory Approval" means any and all approvals, licenses, registrations, or authorizations of any country, federal, supranational, state, or local regulatory agency, department, bureau, or other government entity that are necessary for the commercialisation of any Licensed Product in a given jurisdiction.

"Regulatory Authority" means any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in any jurisdiction in the Territory involved in the granting of Regulatory Approval for, or involved in the regulation of, pharmaceutical products.

"Research and Technical Development Plan" has the meaning ascribed to it in Clause 4.1.

"Research and Technical Development Plan Activities" means the Research and Technical Development Plan Activities allocated to Ascendis or its Affiliates as set forth in a Research and Technical Development Plan.

"Research and Technical Development Plan Expenses" means the following costs and expenses actually incurred by Ascendis or its Affiliates after the Effective Date in carrying out the Ascendis Research and Technical Development Plan Activities:

(A) the out-of-pocket costs incurred by Ascendis or its Affiliates of having the Research and Technical Development Plan Activities performed by approved service providers (including without limitation Third Party manufacturing organisations) in accordance with the applicable Research and Technical Development Plan;

(B) Ascendis FTE Costs; and

(C) any other costs or expenses specifically identified and included in the applicable Research and Technical Development Plan, which, for the avoidance of doubt, may include, without limitation, pre-paid amounts.

"Share Purchase Agreement" shall mean that certain Share Purchase Agreement dated as of even date herewith, by and among Licensee, Ascendis-China Ltd., Ascendis Pharma A/S, Vivo Plenilune IX Limited, and Sofinnova Venture Partners IX, L.P.

"Shareholders Agreement" means that certain Shareholders Agreement dated as of even date herewith, by and among Licensee, Ascendis-China Ltd., Ascendis Pharma A/S, Vivo Plenilune IX Limited, and Sofinnova Venture Partners IX, L.P.

"SDEA" has the meaning ascribed to it in Clause 9.1.

"Sub-Licensee" means any Entity that has been granted a sub-licence by either Party of its rights granted hereunder in accordance with Clause 2.4.

"Technical Information" means any and all: (a) identifiable know-how, data, inventions, discoveries, findings, methods, proprietary information, processes, techniques, materials and other information and technology (whether patentable or not) including formulae, biological materials, practices, test data (including pharmacological, toxicological and clinical information and related reports, statistical analyses, expert opinions and the like), analytical and quality control data, marketing, pricing, distribution, cost and sales data or descriptions; and (b) all Intellectual Property with respect to the items in subsection (a) above other than Patents. For clarity, as used in this Agreement, the term "Technical Information" excludes Patents.

"Territory" means the People's Republic of China, including Hong Kong, Macao and Taiwan.

"Third Party" means any Entity other than Ascendis or its Affiliates or its Sub-Licensees, or the Licensee or its Affiliates or its Sub-Licensees.

"Third Party Claim" means any action, suit or other proceedings brought by a Third Party.

"TransCon Hydrogel" means Ascendis' proprietary [***] hydrogel containing TransCon Linkers

"TransCon Linker" means Ascendis' proprietary linker used in [***] a substrate of interest to various carriers (including [***], which chemical linker [***].

"TransCon [***]" means Ascendis' proprietary [***]-based carrier containing TransCon Linkers.

"Valid Claim" means any claim of a Patent that has not expired or been disclaimed, abandoned or dedicated to the public, or held revoked, unenforceable, unpatentable or invalid (whether through reexamination, reissue, opposition or otherwise) by a decision of a court or governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time frame allowed for appeal.

"VAT" means value added tax as provided for in the Value Added Tax Act 1994 and legislation supplemental thereto, TVA or any other system of value added tax as provided for in Council Directive 2006/112/EC applied in any Member State of the European Union and any other similar turnover, sales or purchase, tax or duty levied by any other jurisdiction whether central, regional or local.

1.2 **Construction**

In this Agreement where the context admits:

(A) references to any statute or statutory provisions shall be deemed to refer to those provisions as amended or re-enacted or as their application is modified by other provisions from time-to-time and any reference to a statutory provision shall include any subordinate legislation made from time-to-time under that provision;

(B) references to “this Agreement” or to any other agreement or document referred to in this Agreement mean this Agreement or such other agreement or document as may be amended, varied, supplemented, modified or novated from time-to-time, and include the Schedules;

(C) references to Clause(s) and Schedule(s) are references to clause(s) and schedule(s) of and to this Agreement, and each of the Schedules shall have effect as if set out in this Agreement;

(D) references to “proprietary” mean Controlled by a Party, but do not infer any requirement of a Patent;

(E) the headings and sub-headings in this Agreement are inserted for convenience only and shall not affect the construction of this Agreement;

(F) the singular includes the plural and vice versa, and references to the masculine, feminine and the neuter shall include all such genders;

(G) references to any Party include its successors and permitted assigns;

(H) the symbol “€” means the lawful currency of the member states of the European Union that adopt the single currency in accordance with the EC Treaty, known as the “Euro”; and

(I) the symbol “$” means the lawful currency of the United States of America, known as the “US Dollar”.

2. **Grants and Restrictions**

2.1 Ascendis hereby grants to the Licensee an exclusive (even as to Ascendis, and subject to the terms and conditions of this Agreement), royalty-free (in accordance with Clause 7) licence (with the right to grant sub-licences subject to Clause 2.4) under Ascendis Patents and Ascendis Technical Information to develop, Manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize Licensed Product in the Field in the Territory. Licensee has the right to grant sublicenses (through one or more tiers) to its Affiliates that are operating companies for China, Hong Kong or other regions in the Territory and such sublicense agreements will be entered into each within [***] ([***]) days after the applicable operating company is incorporated and becomes operational (each such applicable operating company, a “Sublicensed Affiliate”).

2.2 The Licensee hereby grants to Ascendis a non-exclusive, royalty-free, fully-paid, perpetual, irrevocable license (with the right to grant sub-licences subject to Clause 2.4) under the Licensee Program IP and Licensee’s and its Affiliates’ interest in Joint Program IP, in each case that are Controlled by the Licensee or its Affiliates, to make, have made, use, sell, offer for sale or import Licensed Products in any field of use outside the Territory. Ascendis will have the right to convert such non-exclusive license (in whole or in part, at Ascendis’s discretion) to an exclusive license on commercial reasonable terms to be negotiated between the Parties in good faith.

2.3 **Restrictions**

(A) During the term of this Agreement, neither Ascendis nor its Affiliates shall conduct, or intentionally enable, or participate in, or license or otherwise authorize any Third Party to conduct, enable or participate in, the research, development, Manufacture or commercialisation of any Competing Product in the Territory (whether for its own account or for any Third Party). As used in this Clause 2.4, a "Competing Product" shall mean [***].

(B) During the term of this Agreement, the Licensee covenants that it shall not, and Licensee shall procure that its Affiliates and Sub-Licensees shall not, use or exploit the Ascendis Patents or Ascendis Technical Information otherwise than as expressly permitted under the licences granted to Licensee in Clause 2.1. Further, the Licensee shall not grant any license to any Third Party to Licensee's and its Affiliates interest in (i) Program IP [***] and (ii) any Program IP solely relating to the Ascendis Platform Technology [***], in each case of (i) and (ii), without the prior written consent of Ascendis.

2.4 Each Party agrees that:

(A) any and all sub-licences granted under Clauses 2.1 and 2.2 shall be on terms consistent with the terms of this Agreement, contain obligations on each Sub-Licensee to perform and observe terms and conditions similar to those contained herein so far as the same are applicable;

(B) it shall be liable to the other Party for any acts and omissions of its Sub-Licensee that cause any breach of the provisions of this Agreement; and

(C) it shall, within [***] ([***]) days of the grant of each sub-licence, provide the other Party with [***], provided that [***] from such sub-licence: [***].

2.5 Ascendis shall [***] not to commit any acts or omissions that could cause a material breach of any licence agreement pursuant to which Ascendis has rights to Intellectual Property that it has sub-licensed to the Licensee under this Agreement, such that its Third Party licensor terminates or amends such licence agreement in any way that materially adversely affects a licence or other right granted to the Licensee under this Agreement that is used in a Licensed Product being developed (including under an active Research and Technical Development Plan) or commercialised by the Licensee. Ascendis shall not exercise any rights it may have with respect to any such licence agreement, or amend, terminate, or waive any of its rights under such licence agreement in any way that materially adversely affects a licence or other right granted to the Licensee under this Agreement that is used in a Licensed Product being developed (including under an active Research and Technical Development Plan) or commercialised by the Licensee.

2.6 Only the licences granted or retained pursuant to the express terms of this Agreement shall be of any legal force or effect. No other licence rights shall be created by implication, estoppel or otherwise under this Agreement.

2.7 Each Party shall procure that its Affiliates shall comply with the terms and conditions of this Agreement and shall be liable to the other Party for any acts or omissions of such Affiliates which are not in compliance with the terms and conditions of this Agreement.

2.8 During the term of this Agreement, prior to engaging in substantive discussions with a Third Party regarding the license to such Third Party by Ascendis or its Affiliates under the

Ascendis Platform Technology of [***] commercialise Endocrinology Product(s) in the Territory, either by license, option, or otherwise (a "ROFN Opportunity"), Ascendis shall notify Licensee thereof, except to the extent Ascendis cannot grant to Licensee or its Affiliates any rights to such Endocrinology Products in the Territory in light of restrictions imposed on Ascendis or its Affiliates under agreements by and between Ascendis or its Affiliates (on the one hand) and a Third Party (on the other hand) existing as of the "Initial Closing Date" (as such term is defined in the Share Purchase Agreement. No later than [***] ([***]) Business Days after Licensee's receipt of such notice, Licensee shall notify Ascendis whether Licensee wishes to enter into negotiations with Ascendis to negotiate an agreement for Licensee to obtain the right corresponding to such ROFN Opportunity on reasonable commercial terms to be agreed on in good faith ("ROFN License Agreement"). If Licensee does not timely notify Ascendis that it wishes to negotiate for the ROFN Opportunity, or notifies Ascendis that it is not interested in the ROFN Opportunity, Ascendis shall be free to engage with Third Parties discussions of such ROFN Opportunity, and Licensee shall have no further rights under this Clause 2.8 with respect to such ROFN Opportunity. If Licensee timely notifies Ascendis it wishes to negotiate an agreement for such ROFN Opportunity, the Parties shall enter into good faith negotiations not to exceed [***] ([***]) days with the goal of finalizing the terms of and executing such ROFN License Agreement. If after the expiration of such [***] ([***])-day period (the "ROFN Negotiation Stop Date"), the Parties have not executed such ROFN License Agreement, Ascendis shall be free to engage with Third Parties discussions of such ROFN Opportunity [***], and Licensee shall have no further rights under this Clause 2.8 with respect to such ROFN Opportunity. Notwithstanding any other provision of this Clause 2.8, in no event shall this Clause 2.8 limit in any way the ability of Ascendis or its Affiliates to engage in discussions with a Third Party for [***] to such Third Party under the Ascendis Platform Technology to [***] commercialise an Endocrinology Product so long as such discussions are not in conflict with Ascendis's obligations under Clause 2.3(A), and any such discussions shall not be deemed a "ROFN Opportunity" for which this Clause 2.8 applies.

2.9 In the event that Ascendis discontinues the development or commercialization of Licensed Product outside the Territory, or if Licensee discontinues the development or commercialization of Licensed Product in the Territory for safety, efficacy and/or regulatory reasons relating to Licensed Product (a "Qualifying Discontinuance"), Ascendis or Licensee, as the case may be, shall promptly inform the other Party of such Qualifying Discontinuance and shall provide relevant data and documentation which forms the basis of such decision to the other Party. In the event of a Qualifying Discontinuance, upon the Licensee's request, Ascendis shall provide to the Licensee [***] for its other Endocrinology Products which are [***] and for which Ascendis has not granted any Third Party [***] in the Territory, and the Licensee may elect to (i) continue activities with respect to the relevant Licensed Product in the Territory, or (ii) substitute the relevant Licensed Product with one of such other Endocrinology Products, [***], in which event such Endocrinology Product will become a Licensed Product and the Parties shall execute an amendment to this Agreement to memorialize the same. Further, if Licensee requires any technology transfer in connection with such substitution under clause (ii) of the preceding sentence, the Parties [***] the scope and timing for such transfer, as well as FTE-based payments to be made to Ascendis with respect to such transfer activities.

3. **Technical Information and Patents**

3.1 Within [***] ([***]) days of the Effective Date, Ascendis shall deliver and provide to the Licensee the items of Ascendis Technical Information listed in Schedule 2.

3.2 Ascendis shall use its Diligent Efforts to provide the Licensee with any additional Technical Information that is not specified in Schedule 2 but is Controlled by Ascendis and/or its Affiliates relating to the Ascendis Technical Information or Ascendis Platform Technology during the term of this Agreement that is necessary or useful for the Licensee to make, have made, use, sell, offer for sale or import Licensed Product in the Field in the Territory. [***].

3.3 Upon the Licensee's written request, but in no event more than [***] during the term of this Agreement, Ascendis shall provide, [***] to the Licensee a written update (as of the date the request is received by Ascendis) of the Licensed Product Patents in Schedule 1 and/or Ascendis Technical Information in Schedule 2.

4. **Development and Commercialisation**

4.1 Within [***] days following the Effective Date, the Parties shall agree to a research and technical development plan (the "Research and Technical Development Plan") that sets forth the Parties' respective Research and Technical Development Plan Activities, which may be amended from time to time by the JDC in accordance with this Agreement. The Parties shall perform and complete, or cause the performance and completion of, their respective Research and Technical Development Plan Activities, and deliver to each other a summary of the results (including raw data if reasonably requested by a Party), samples and reports arising therefrom in accordance with each Research and Technical Development Plan within [***] ([***]) days following completion thereof.

4.2 The Licensee shall provide Ascendis with a draft of each Research and Technical Development Plan. The Licensee shall consider, in good faith, any comments regarding each draft Research and Technical Development Plan that Ascendis provides to the Licensee within [***] ([***]) days of Ascendis' receipt of such draft Research and Technical Development Plan. In addition, the Licensee shall keep Ascendis informed of the progress of the development of each Licensed Product against the applicable Research and Technical Development Plan at each meeting of the JDC pursuant to Clause 4.6(A).

4.3 The Licensee shall be solely responsible for any clinical trial activities carried out as part of its development and commercialisation activities in the Territory.

4.4 The Licensee shall use Diligent Efforts to develop and commercialise Licensed Product in the Field in the Territory.

4.5 Each Party shall conduct all development of Licensed Product in compliance with current Good Laboratory Practice, Good Clinical Practice and Good Manufacturing Practice, in each case, where applicable. Neither Party shall use any person that has been debarred, disqualified or banned from practising medicine to perform activities under this Agreement, and each Party shall immediately notify the other Party in writing if any person performing activities under this Agreement is disqualified, debarred or banned from practising medicine.

4.6 **Joint Development Committee**

(A) **Formation of JDC**

Promptly after the Effective Date, the Parties will form a Joint Development Committee comprised of three (3) representatives of Ascendis and three (3) representatives of the Licensee for the first Research and Technical Development Plan (and will promptly form a JDC following agreement between the Parties in relation to each additional Research and Technical Development Plan). Ascendis agrees that it shall not have the right to nominate representatives of the Licensee to the JDC notwithstanding its ownership in the Licensee.

One representative of the Licensee at the JDC will be selected to act as the chairperson of the JDC. The JDC will meet at least [***] ([***]) times per year during the term of a Research and Technical Development Plan. Such meetings may be conducted by videoconference, teleconference or in person, as agreed by the Parties. The JDC will agree upon the time and location of the meetings. The chairperson, or his or her designee, will circulate an agenda for each meeting approximately [***] before the date scheduled for the meeting, and will include all matters requested to be included on such agenda by either Party. The chairperson, or his or her designee, will take complete and accurate minutes of all discussions occurring at the JDC meetings and all matters decided upon at the meetings except that matters reflecting legal advice of counsel will not be included in such minutes. A copy of the draft minutes of each meeting will be provided to each Party by the chairperson, or his or her designee, after each meeting, and such minutes will be reviewed by the JDC members, any needed changes discussed and final minutes agreed to and provided to each Party within [***] ([***]) days after each meeting unless otherwise agreed. A reasonable number of additional representatives of a Party may attend meetings of the JDC in a non-voting capacity. Each Party is responsible for its personnel and travel costs and expenses associated with attending meetings.

(B) **JDC functions and powers**

The responsibilities of the JDC will be as follows:

(1) encouraging and facilitating communication between the Parties with respect to the development of Licensed Product(s)) and the Research and Technical Development Plan Activities;

(2) [***] the applicable Research and Technical Development Plan's objectives, goals and schedules, and reviewing and approving amendments to the applicable Research and Technical Development Plan, [***]

(3) [***], discussing and [***] the progress of the development of Licensed Product, each Party's progress with respect to the Research and Technical Development Plan Activities for which it is responsible and each Party's diligence in carrying out its responsibilities under the applicable Research and Technical Development Plan; and

(4) carrying out the other duties and responsibilities described for it in this Agreement.

(C) **JDC decision making**

(1) All decisions of the JDC will be made by unanimous vote, with each of Ascendis and Licensee having one vote and the decisions will be recorded in the JDC minutes. If after reasonable discussion and consideration of each of the Parties' views on a particular matter before the JDC, the JDC is unable to reach a decision by unanimous vote on that matter, then [***]

The JDC shall not have any authority other than that expressly set forth above and, specifically, shall have no authority: (x) to amend or interpret this Agreement; (y) to determine whether or not a Party has met its diligence or other obligations under the Agreement; or (z) to determine whether or not a breach of this Agreement has occurred.

(D) **Termination of JDC**

The JDC shall terminate in respect of a Research and Technical Development Plan upon completion by both Parties of their respective Research and Technical Development Plan Activities, unless the Parties otherwise agree.

5. **Manufacturing**

5.1 Concurrently with the execution of this Agreement, the Parties have entered into that certain clinical supply agreement (the "Clinical Supply Agreement") pursuant to which Ascendis will supply Licensed Product to Licensee for Licensee's conduct of clinical trials for the Licensed Product in the Territory on the terms and conditions set forth in the Clinical Supply Agreement. The Parties shall discuss and negotiate in good faith the terms and conditions for the supply by Ascendis of Licensed Product to the Licensee for commercial use upon the written request of Licensee, and in any event starting no later than the date that is [***] ([***]) days after the initiation of the first pivotal clinical trial for the Licensed Product conducted by or behalf of Licensee in the Field and in the Territory.

5.2 The Licensee shall, and it shall procure that its Affiliates and any Sub-Licensees shall:

(A) [***] relating to the sale of Licensed Product comply with Applicable Laws and are marked, where required, with all relevant patent numbers; and

(B) conduct all packaging and distribution in accordance with current Good Manufacturing Practice and Good Distribution Practice.

6. **Regulatory**

6.1 The Licensee shall have the sole responsibility for obtaining and maintaining, and shall own, all Regulatory Approvals for Licensed Product developed under this Agreement from Regulatory Authorities in each of the jurisdictions in the Territory in the Field.

6.2 Ascendis hereby grants to the Licensee, its Affiliates and Sub-licensees the right to access, reference and utilize any data (including clinical trial data) or regulatory filings generated and/or filed by or on behalf of Ascendis or its Affiliates or other licensees (in each case, to the extent Controlled by Ascendis or its Affiliates) with respect to Licensed Product(s)) in connection with the development, Manufacturing and commercialisation by the Licensee, its Affiliates and Sub-licensees of Licensed Product(s) in the Territory, free of additional charge, as set forth herein. Upon written request from Licensee to be provided access to any such information, Ascendis shall provide such access to Licensee within a reasonable time frame, taking into account the development and regulatory activities conducted by or on behalf of Ascendis for the Licensed Products outside of the Territory. Ascendis hereby represents and warrants that, as of the Effective Date, it and/or its Affiliates Control all data and regulatory filings generated and/or filed by or on behalf of Ascendis or its Affiliates or other licensees with respect to the Licensed Product and Ascendis has the right to grant the right to access, reference and utilization to Licensee, its Affiliates and Sub-licensees thereto. During the Term, Ascendis and/or its Affiliates shall maintain the right to all data and regulatory filings generated and/or filed by or on behalf of Ascendis or its Affiliates or other licensees with respect to the Licensed Product (including by reserving the rights from any Third Party generating, filing and/or having rights to any and all such data and/or regulatory filings) so that Ascendis and/or its Affiliates retains Control of such data and regulatory filings and can grant the right to access, reference and utilization to Licensee, its Affiliates and Sub-licensees under this Section 6.2.

6.3 The Licensee hereby grants to Ascendis the right to access, reference and utilize any data (including clinical trial data) or regulatory filings generated and/or filed by or on behalf of the Licensee or its Affiliates or sublicensees (in each case, to the extent Controlled by Licensee or its Affiliates) with respect to Licensed Product(s) in connection with the development, Manufacturing and commercialisation by Ascendis, its Affiliates or other licensees of Licensed Product(s) outside the Territory, free of additional charge, as set forth herein. Upon written request from Ascendis to be provided access to any such information, Licensee shall provide such access to Ascendis within a reasonable time frame, taking into account the development and regulatory activities conducted by or on behalf of Licensee for the Licensed Products in the Field in the Territory. During the Term, Licensee and/or its Affiliates shall maintain the right to all data and regulatory filings generated and/or filed by or on behalf of Licensee or its Affiliates or Sub-licensees with respect to the Licensed Product (including by reserving the rights from any Third Party generating, filing and/or having rights to any and all such data and/or regulatory filings) so that Licensee and/or its Affiliates retains Control of such data and regulatory filings and can grant the right to access, reference and utilization to Ascendis, its Affiliates and other licensees under this Section 6.2.

6.4 The Licensee undertakes to comply, and to procure that its Sub-Licensees and contractors comply, with all requirements of Regulatory Authorities and/or Applicable Law and relevant guidance.

6.5 Ascendis shall provide assistance and information as reasonably requested by the Licensee in support of such regulatory activities[***].

7. Payments

7.1 Upfront

As a one-time, non-refundable consideration of the rights and licence granted by Ascendis to Licensee under this Agreement, Licensee shall issue and transfer to Ascendis [***] Series A-1 Preferred Shares in VISEN Pharmaceuticals, corresponding to a total value of US[***] at the Effective Date.

7.2 Research and development funding

The Licensee shall pay or reimburse (as applicable) Ascendis for the Research and Technical Development Plan Expenses in accordance with the schedule set forth in the Research and Technical Development Plans.

7.3 Taxes

In the event that the Licensee is required, under applicable laws, to withhold any deduction or tax from any payment due to Ascendis under this Agreement, such amount shall be deducted from the payment to be made by the Licensee, paid to the proper taxing authority, provided that the Licensee shall take reasonable and lawful actions to avoid and minimise such withholding and promptly notify Ascendis so that Ascendis may take lawful actions to avoid and minimise such withholding. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time-to-time in effect.

All sums payable by the Licensee under or pursuant to this Agreement [***] VAT (if applicable). The taxable supply of services made under or in connection with this Agreement by Ascendis to the Licensee are [***]. The Parties agree that they will undertake commercially reasonable efforts to minimize or eliminate any VAT liability, including but not limited to [***].

7.4 **Interest**

Where any fees, milestones or other sums payable by the Licensee to Ascendis hereunder remain unpaid after the date on which they became due, the Licensee shall pay to Ascendis interest calculated from the date upon which the sums became due until payment thereof at the rate, to the extent permitted by applicable law, equal to the average one-month US Dollar London Interbank Offered Rate (LIBOR) as determined for each Quarterly Period on the last Business Day of such Quarterly Period (it being understood that if such rate is below zero percent (0%) for any period it shall be deemed to be zero percent (0%) for such period for the purposes of this Clause 7.4) plus [***] percent ([***]%).

8. **Records and Auditing**

8.1 Each Party will maintain complete and accurate books, records and accounts used for the determination of any payment obligations under this Agreement, which books, records and accounts will be retained by such Party until [***] ([***]) years after the end of the period to which such books, records and accounts pertain. The Licensee shall make such books, records and accounts available to Ascendis for an additional [***] ([***]) years if reasonably available and required by the applicable tax authority.

9. **Pharmacovigilance**

9.1 After the execution of this Agreement, the Parties shall promptly, and in any event before the Licensee starts any clinical development activities, agree on the terms of a safety data exchange agreement (the "SDEA") for the collection, reporting and exchange of safety information. The scope of the SDEA shall also include the Licensee's Affiliates and Sub-Licensees, as applicable.

9.2 Each Party shall notify the other Party of any "serious adverse experience" or "unexpected adverse experience" (as defined below) and will manage the same, both in accordance with the terms of the SDEA. For the purpose of this Clause 9.2, "serious adverse experience" and "unexpected adverse experience" shall have the meaning assigned by relevant regulations (to the extent applicable). To the extent relevant regulations require harmonisation or are not applicable, then each of the foregoing terms shall be as defined in the SDEA.

10. **Confidentiality**

10.1 During the term of this Agreement, and for a period of [***] ([***]) years thereafter, the Licensee agrees to keep secret Ascendis' Confidential Information, to use the same exclusively as permitted under this Agreement, and to disclose the same only to those of its employees, contractors, consultants, Affiliates and Sub-Licensees to whom and to the extent that such disclosure is reasonably necessary in order to exercise its rights and perform its obligations under this Agreement.

10.2 During the term of this Agreement, and for a period of [***] ([***]) years thereafter, Ascendis agrees to keep secret the Licensee's Confidential Information, to use the same exclusively as permitted under this Agreement, and to disclose the same only to those of its employees, contractors, Affiliates, Sub-Licensees and licensees to whom and to the extent that such disclosure is reasonably necessary in order to exercise its rights and perform its obligations under this Agreement.

10.3 Each Party shall procure that all its employees, contractors, Affiliates and Sub-Licensees who have access to any Confidential Information of the other to which the obligations of Clauses 10.1 or 10.2 as the case may be apply, shall be made aware of, subject to, and comply with those obligations. Without limiting the foregoing, each Party shall take at least those measures it employs to protect its own confidential information of a similar nature to protect the other Party's Confidential Information, but in any event no less than reasonable care.

10.4 The foregoing obligations of Clauses 10.1 and 10.2 shall not apply to any Confidential Information of the disclosing Party which:

(A) prior to the recipient Party's receipt thereof from the disclosing Party, was in the possession of the recipient Party without any breach of confidentiality and at its free disposal;

(B) is subsequently lawfully disclosed to the recipient Party without any breach of confidentiality by an independent Third Party, and at the recipient Party's free disposal;

(C) is or becomes generally available to the public through no act or default of the recipient Party or its agents, contractors or employees; or

(D) is independently developed by the receiving Party without the benefit of any Confidential Information disclosed hereunder, as demonstrated by documented evidence prepared contemporaneously with such independent development.

10.5 Notwithstanding the foregoing, a Party and its Affiliates and Sub-Licensees may use and disclose the Confidential Information of the other Party:

(A) if it is required to be disclosed by law, regulation or action of any governmental agency or authority, including as may be required in connection with any filings made with, or by the disclosure policies of a major stock exchange; provided that the Party seeking to disclose the Confidential Information of the other Party: (i) promptly informs the other Party (prior to making any such disclosures, if practicable) and cooperates with the other Party in seeking a protective order or other appropriate remedy (including redaction); and (ii) whenever it is possible to obtain confidential treatment, request confidential treatment of such information;

(B) as reasonably necessary to obtain or maintain any Regulatory Approval, including to conduct preclinical studies and clinical trials and for pricing approvals, for any Licensed Product, provided that, the disclosing Party shall use commercially reasonable efforts to limit disclosure of the Confidential Information outside such regulatory agency and to otherwise maintain the confidentiality of the Confidential Information; or

(C) as reasonably necessary to exercise its rights or fulfil its obligations under this Agreement.

10.6 The Licensee and its Affiliates and Sub-Licensees may disclose the Confidential Information of Ascendis to contractors, consultants and other service providers in connection with the development or Manufacture of Licensed Product(s) under conditions of confidentiality at least as restrictive as those contained in this Clause 10 and/or as is standard for similar deals in the biotechnology industry.

10.7 If a Party concludes that a copy of this Agreement must be filed with the United States Securities Exchange Commission or other regulatory agency ("SEC") (or equivalent foreign agency or a securities exchange), such Party will use all reasonable efforts to provide the other Party with a copy of this Agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, and to provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions. The filing Party will take such other Party's reasonable comments into consideration before filing the Agreement.

10.8 Each Party ("Publishing Party") shall submit to the other Party manuscripts, including abstracts, and texts of poster presentations and other external presentations containing the other Party's Confidential Information at least [***] ([***]) days prior to presentation or submission for publication for purposes of allowing the other Party to comment on the manuscript or text; provided that the other Party may require the Publishing Party, by giving notice in writing to the Publishing Party within [***] ([***]) days of the receipt of such manuscript, abstract, text or other external presentations from the Publishing Party to redact certain information or delay submission for publication or presentation of such manuscript, abstract, text or other external presentation if, in the reasonable opinion of the other Party such delay is necessary in order to permit the filing of any patent application or to protect the other Party's Confidential Information contained in such manuscript, abstract, text or other external presentation.

10.9 The Licensee, in accordance with its internal policies and procedures, shall have the right to publish all studies, clinical trials and results thereof on the clinical trial registries that are maintained by or on behalf of the Licensee. Ascendis shall not publish any studies, clinical trials or results thereof on its clinical trial registry, provided however, that Ascendis may include on Ascendis' clinical trial registry a link to the Licensee's clinical trial registry.

10.10 Notwithstanding the foregoing, each Party shall have the right to disclose the terms and conditions of this Agreement: (i) in confidence (i.e., pursuant to a written confidentiality agreement containing terms at least as stringent as those contained in this Agreement) to any bona fide potential or actual investor, investment banker, auditor, counsel, acquirer or merger target; and (ii) subject to the prior written consent of the other Party, such consent not to be unreasonably withheld, for the purpose of a public offering or private placement of shares and/or securities.

11. **Intellectual Property**

11.1 All Patents and Technical Information and other Intellectual Property owned or Controlled by a Party prior to the Effective Date shall remain owned or Controlled by the respective Party.

11.2 Ascendis and the Licensee acknowledge and agree that as between them:

(A) Ascendis (or its Affiliates) shall own all right, title and interest in and to any and all Ascendis Patents (except for Ascendis Patents within the Joint Program IP), Ascendis Technical Information (except for Ascendis Technical Information within the Joint Program IP) and Ascendis Program IP;

(B) the Licensee shall own all right, title and interest in and to any and all Licensee Program IP; and

(C) the Licensee and Ascendis (or its Affiliates) shall each own an undivided fifty percent (50%) right, title and interest in and to any and all Joint Program IP. For the avoidance of doubt, subject to the licences granted under this Agreement, each Party shall be free to exploit, transfer or encumber its own interest in the Joint Program IP without the consent of, and without accounting to, the other Party. For those jurisdictions where a specific license is required for a joint owner of Joint Program IP to practice such Joint Program IP in such jurisdictions: (i) Ascendis hereby grants to Licensee a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable license under Ascendis's right, title and interest in and to all Joint Program IP to use such Joint Program IP in accordance with the terms of this Agreement; and (ii) Licensee hereby grants to Ascendis a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable license under Licensee's right, title and interest in and to all Joint Program IP to use such Joint Program IP in accordance with the terms of this Agreement. Each Party shall promptly notify the other Party after it first learns of the conception of a Joint Program IP by such Party, its employees, officers, or independent contractors, and provide the other Party with a detailed report of the underlying data, results, experimental procedures related to, and inventors of, such Joint Program IP.

11.3 Notwithstanding the foregoing, [***].

12. **Prosecution, Maintenance and Defence**

12.1 Subject to Clause 12.4, Ascendis shall, at its own expense and in its sole discretion, have the right to file, prosecute, maintain and defend the Ascendis Patents that are not Joint Program IP Patents (as defined in Clause 12.3(A) (including without limitation Licensed Product Patents as well as any Ascendis Patent claiming Ascendis Platform Technology that are not Joint Program IP Patents). Solely with respect to the Licensed Product Patents in the Territory that are not within the Joint Program IP, Ascendis will promptly provide the Licensee with drafts of all proposed filings and correspondence (including without limitation the initial application as well as any material correspondence with any Intellectual Property Office in the Territory related to any filings) in a manner that allows the Licensee a reasonable opportunity for review and comment (and in any event no less than [***] ([***]) days, if and when possible) before such filings are due. Ascendis will consider all of the Licensee's reasonable suggestions, recommendations and instructions concerning the preparation, filing, prosecution, defence and maintenance of any such Patents (including without limitation any suggestion or recommendation [***]), provided that such reasonable suggestions, recommendations and instructions are provided to Ascendis within [***] ([***]) days of the Licensee receiving any such proposed filings and correspondence. If Ascendis does not wish to file, prosecute or maintain any such Licensed Product Patent which is not within the Joint Program IP, or if Ascendis wishes to allow any such Patent to lapse, in each case, solely within the Territory, then [***], Ascendis shall notify Licensee in writing of such decision at least [***] ([***]) days prior to any action relating to such Patent is required, and Licensee shall then have the option, at its sole discretion, to file, prosecute, and/or maintain such Patent, at its sole cost and expense.

12.2 Subject to Section 12.4, the Licensee shall, at its own expense and in its sole discretion, have the right to file, prosecute, maintain and defend any Patent within the Licensee Program IP. If Licensee does not wish to file, prosecute or maintain any such Patent within the Licensee Program IP, or if Licensee wishes to allow any such Patent to lapse, in each

case, solely outside of the Territory, then [***], Licensee shall notify Ascendis in writing of such decision at least [***] ([***]) days prior to any action relating to such Patent is required, and Ascendis shall then have the option, at its sole discretion, to file, prosecute, and/or maintain such Patent, at its sole cost and expense.

12.3 **Joint Program IP**

(A) Subject to Clause 12.4, the Prosecuting Party (as defined below) shall select outside patent counsel ("Outside Patent Counsel") at its sole discretion to file, prosecute and maintain any Patent within the Joint Program IP in the joint names of the Parties ("Joint Program IP Patent"). [***] shall have the first right, at its sole expense and in its sole discretion, to engage Outside Patent Counsel to file, prosecute and maintain all Joint Program IP Patents, and [***] shall have the backup right to file, prosecute, and maintain such Joint Program IP Patents in the Territory in accordance with Clause 12.3(C). The Party that exercises its right to file, prosecute and maintain a particular Joint Program IP Patent in accordance with this Clause 12.3 shall be referred to as the "Prosecuting Party".

(B) With respect to Joint Program IP Patents, the Prosecuting Party will (or will cause Outside Patent Counsel to) promptly provide the other Party with drafts of all proposed filings and correspondence (including without limitation the initial application as well as any material correspondence with any Intellectual Property Office related to any filings) in a manner that allows the other Party a reasonable opportunity for review and comment (and in any event no less than [***] ([***]) days, if and when possible, before such filings are due). The Prosecuting Party will (or will cause Outside Patent Counsel to) consider all of the other Party's reasonable suggestions, recommendations and instructions concerning the preparation, filing, prosecution, defence and maintenance of any such Joint Program IP Patents (including without limitation any suggestion or recommendation [***]), provided that such reasonable suggestions, recommendations and instructions are provided to the Prosecuting Party (or Outside Patent Counsel) within [***] ([***]) days of the other Party receiving any such proposed filings and correspondence.

(C) If [***] as the Prosecuting Party elects: (1) not to file, prosecute or maintain a Joint Program IP Patent (whether in one or more jurisdictions); or (2) to allow any such Patent to lapse or become abandoned or unenforceable, in each case, in accordance with Clause 12.3(A), then [***] shall notify [***] in writing at least [***] ([***]) days prior to the lapse or abandonment of any such Patent. Thereafter, [***] may, but is not required to, undertake, at its sole expense and in its sole discretion, and using Outside Patent Counsel, the prosecution and maintenance of such Joint Program IP Patent, but solely within the Territory, and in such case, [***] shall become the Prosecuting Party with respect to such Patent in the Territory.

12.4 Notwithstanding any other provision of this Clause 12, [***]

12.5 The Parties agree to cooperate reasonably in the filing, prosecution and maintenance of all Patents as set forth under this Clause 12 including providing relevant Technical Information to the prosecuting Party (as determined in accordance with this Clause 12), obtaining and executing necessary powers of attorney and assignments by the named inventors, obtaining execution of such other documents which may be needed in the filing, prosecution and maintenance of each such Patent, and, as requested, updating each other regarding the status of each such Patent, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession and Control that is reasonably necessary to prosecute and maintain such Patents.

13. **Enforcement of Patent Rights and Defence of Third Party Claims**

13.1 **Infringement by a Third Party**

(A) In the event of Ascendis or the Licensee becoming aware of any suspected infringement or any unauthorised use by a Third Party of any of the Ascendis Patents, Ascendis Technical Information, Ascendis Program IP, Licensee Program IP, and/or the Joint Program IP in the Field in the Territory, the Party becoming aware of the same shall promptly notify the other Party.

(B) Where such suspected infringement or unauthorised use is of the Ascendis Patents or Ascendis Technical Information (including those within the Joint Program IP and/or Ascendis Program IP), in each case (i) outside the Territory, or (ii) inside the Territory but outside the Field, Ascendis shall, at its own expense, have the exclusive right, but not the obligation, to take or threaten any legal action that it deems appropriate to halt such suspected infringement and to retain any amounts recovered in respect of such suspected infringement or unauthorised use. Termination and/or settlement of the litigation are at the sole discretion of Ascendis (i.e., without the prior consent of the Licensee), provided such termination or settlement does not impose a liability (monetary or otherwise) on Licensee or limit the rights of Licensee under this Agreement, or otherwise materially impair Licensee's rights in the relevant Ascendis Patent in each case without Licensee's prior written consent.

(C) Where such suspected infringement or unauthorised use is of the Ascendis Patents Ascendis Technical Information (including those within the Joint Program IP and/or any Ascendis Program IP), in each case in the Field in the Territory, the Licensee shall, at its own expense, have the first right, but not the obligation to take or threaten any legal action that it deems appropriate to halt such suspected infringement (provided that [***]). Each Party shall retain the following percent of any remaining amounts recovered in respect of such suspected infringement or unauthorised use after the Licensee has recouped its expenses: the Licensee shall retain [***] percent ([***]%) and Ascendis shall retain [***] percent ([***]%). Termination and/or settlement of the litigation are at the sole discretion of the Licensee (i.e., without the prior consent of Ascendis), provided such termination or settlement does not impose a liability (monetary or otherwise) on Ascendis or limit the rights of Ascendis under this Agreement, or otherwise materially impair Ascendis's rights in the relevant Ascendis Patent in each case without Ascendis's prior written consent.

(D) If Ascendis wishes to take or threaten legal action and the Licensee has the first right to do so under Clause 13.1(C), but does not do so within [***] ([***]) days of becoming aware of potential infringement, then Ascendis may take or threaten such legal action and the Licensee shall, at Ascendis' request, lend its name where necessary or desirable to proceedings relating to such action and provide reasonable assistance in such proceedings. In such circumstances, Ascendis shall control the conduct of the action but shall consult the Licensee in good faith with regard to significant decisions. Each Party shall retain the following percent of any remaining amounts recovered in respect of such suspected infringement or unauthorised use after Ascendis has recouped its expenses: Ascendis shall retain an amount equal to [***] percent ([***]%) and the Licensee shall retain the remaining [***] percent ([***]%). Termination and/or settlement of the litigation are at the sole discretion of Ascendis (i.e., without the prior consent of the Licensee).

(E) Each Party shall provide to the Party enforcing any such rights under this Clause 13.1 reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by Applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any important aspects of such enforcement, including determination of litigation strategy and filing of important papers to the competent court.

13.2 **Defence of Third Party Claims**

(A) In the event that the development or commercialisation of a Licensed Product results in action by a Third Party against a Party (or its Affiliates or Sub-Licensees) for infringement or unauthorised use of Intellectual Property or confidential information anywhere in the Territory, such Party shall promptly notify the other Party in writing.

(B) Each Party (or its Affiliates or Sub-Licensees) against whom such action is brought shall: (i) have the right but not the obligation to defend such action; (ii) have the right to be represented by separate legal advisors; (iii) keep the other Party informed of, and assist and co-operate with the other Party in, any such action; and (iv) bear its own costs.

14. **Warranties**

14.1 Each Party warrants to the other Party that it:

(A) is free to enter into this Agreement and to carry out its obligations hereunder without violating any obligation owed by it or any of its Affiliates to any Third Party;

(B) shall not, during the existence of this Agreement, enter into any assignments, licences, obligations, charges or assignments, either written, oral or implied, which are or shall be inconsistent with this Agreement;

(C) has obtained all necessary corporate approvals to enter into and execute this Agreement;

(D) has never been debarred, disqualified or banned from practising medicine and that it is not under investigation by any Regulatory Authority for debarment, disqualification or any similar regulatory action in any country.

14.2 Ascendis represents and warrants to the Licensee that, as of the Effective Date, Ascendis:

(A) Controls the Ascendis Patents and Ascendis Technical Information in the Field in the Territory;

(B) has the right to grant to the Licensee the rights and licences granted to the Licensee under the terms and conditions of this Agreement,

(C) has the right to provide and disclose to the Licensee the Ascendis Technical Information that it provides or discloses to the Licensee under the terms and conditions of this Agreement;

(D) itself and its employees have not received notice of any actions, lawsuits, claims or arbitration or material adverse proceedings (other than on-going routine patent prosecution matters) in any way relating to the Ascendis Patents, Ascendis Technical Information or Ascendis Platform Technology; and

(E) is not, to [***] its knowledge, aware that the use of Licensed Product Patents in Schedule 1, the Ascendis Patents existing as of the Effective Date, and/or Ascendis Technical Information listed in Schedule 2, for development or commercialisation of a Licensed Product infringes any Third Party's Patent.

(F) there are no patents, patent applications or Technical Information that are owned or in-licensed by Ascendis and/or its Affiliates that Ascendis and/or its Affiliates do not Control and are not included in the license granted to Licensee under this Agreement, which would be infringed by or would otherwise cover the development, manufacture and/or commercialization of the Licensed Product in the Field in the Territory. During the Term, Ascendis and/or its Affiliates shall maintain the Control of patents, patent applications and/or Technical Information that are then-owned or then-in-licensed by Ascendis and/or its Affiliates that would be infringed by or would otherwise cover the development, manufacture and/or commercialization of the Licensed Product in the Field in the Territory (including by reserving such rights from any Third Party carrying out the development, manufacture and/or commercialization of the Licensed Product on behalf of or under a license from Ascendis or its Affiliates) so that such patents, patent applications and/or Technical Information are included in the license granted to Licensee hereunder; provided, that for clarity this provision shall not be deemed to impose any obligation on Ascendis to obtain ownership or license rights to any patents, patent applications, Technical Information, or intellectual property rights of any Third Party.

14.3 EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO INTELLECTUAL PROPERTY RIGHTS OR CONFIDENTIAL INFORMATION SUPPLIED BY IT TO THE OTHER PARTY HEREUNDER, AND EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT.

15. **Indemnification**

15.1 Except as provided in Clause 15.2 below, the Licensee shall indemnify, defend and hold harmless Ascendis and its Affiliates, and their respective directors, officers, employees and agents (each an "Ascendis Indemnitee") from and against all Losses arising out of or resulting from any Third Party Claims to the extent such Losses result from or arise out of: (a) the activities performed by the Licensee in connection with the exercise of its rights or obligations under this Agreement (including the exploitation of the Licensed Product(s) in the Territory); (b) breach by the Licensee of the representations and warranties provided in Clause 14; (c) gross negligence, recklessness or wilful misconduct by the Licensee; or (d) violation of Applicable Law by the Licensee. The indemnification obligations set forth in this Clause 15.1 shall not apply to the extent that any such Losses arising from such Third Party Claim arose or resulted from the events specified in Clause 15.2(a)-(d).

15.2 Except as provided in Clause 15.1 above, Ascendis shall indemnify, defend and hold harmless the Licensee, its Affiliates, and their respective directors, officers, employees and agents (each a "Licensee Indemnitee") from and against all Losses arising out of or resulting from any Third Party Claims to the extent such Losses result from or arise out of: (a) the activities performed by Ascendis, its Affiliates, and Sublicensees in connection with the exercise of its rights or obligations under this Agreement, including the exploitation of the

Licensed Product(s) outside of the Territory; (b) breach by Ascendis of the representations and warranties provided in Clause 14; (c) gross negligence, recklessness or wilful misconduct by Ascendis, its Affiliates, and Sublicensees; or (d) violation of Applicable Law by Ascendis, its Affiliates, and Sublicensees. The indemnification obligations set forth in this Clause 15.2 shall not apply to the extent that any such Third Party Claim arose or resulted from the events specified in Clause 15.1(a)-(d).

15.3 In the event that an Ascendis Indemnitee or a Licensee Indemnitee, as applicable (hereinafter an "Indemnified Party") seeks indemnification under this Clause 15, such Indemnified Party shall: (i) give prompt notice to the indemnifying Party of any such Third Party Claim; (ii) permit the indemnifying Party to assume direction and control of the defence of such Third Party Claim (including decisions regarding its settlement or other disposition, which may be made in the indemnifying Party's sole discretion except as otherwise provided herein); (iii) assist the indemnifying Party at the indemnifying Party's expense in defending such Third Party Claim; and (iv) not compromise or settle such Third Party Claim without the indemnifying Party's prior written consent, which shall not be unreasonably withheld or delayed. The failure to deliver written notice to the indemnifying Party within a reasonable time after the commencement of any such Third Party Claim, to the extent prejudicial to its ability to defend such Third Party Claim, shall relieve the indemnifying Party of any obligation to the Indemnified Party under this Clause 15. The Indemnified Party may participate in the defence of such Third Party Claim through counsel of its choice, but the reasonable cost of such counsel shall be borne solely by the Indemnified Party. It is understood that only Ascendis or the Licensee may claim indemnity under this Clause 15 (on its own behalf or on behalf of its Indemnified Parties), and other Indemnified Parties may not directly claim indemnity hereunder. No compromise or settlement of any Third Party Claim may be effected by the indemnifying Party without the Indemnified Party's prior written consent (which consent shall not be unreasonably withheld or delayed), unless: (a) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnified Party; (b) the sole relief provided is monetary damages that are paid in full by the indemnifying Party; and (c) the Indemnified Party's rights under this Agreement are not adversely affected. The Indemnified Party shall have no right to settle any such Third Party Claim without the prior written consent of the indemnifying Party (and any such settlement without the prior written consent of the indemnifying Party shall relieve the indemnifying Party of its obligations under this Clause 15), unless: (x) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnifying Party; (y) the sole relief provided is monetary damages that are paid in full by the Indemnified Party; and (z) the indemnifying Party's rights under this Agreement are not adversely affected.

16. **Limitation of Liability**

16.1 Subject to Clause 16.2, neither of the Parties nor any of their Affiliates shall be liable to each other under any contract, negligence, strict liability or other legal or equitable theory for indirect, incidental, special, punitive, exemplary or consequential damages arising out of or resulting from this Agreement. The foregoing shall not limit:

(A) the obligations of either Party from and against Third Party claims under Clauses 15.1 or 15.2 to the extent that such Third Party has been awarded such damages;

(B) the liability of a Party as a result of its breach of Clause 10; or

(C) the liability of either Party under Clause 2.3.

16.2 Neither Party limits or excludes its liability for fraud, fraudulent concealment or fraudulent misrepresentation, nor for death or personal injury arising from its negligence.

16.3 Ascendis and Ascendis Pharma A/S shall be jointly and severally liable for any liabilities incurred by or on behalf of Ascendis under this Agreement.

17. **Term and Survival**

17.1 This Agreement shall commence with effect from the Effective Date and shall continue for so long as a Valid Claim of an Ascendis Patent exists in the Territory, unless terminated earlier pursuant to Clause 18.

17.2 On the expiration or other termination of this Agreement each Party shall continue to be bound by Clauses 2.2 (solely in the event of expiration, or as it may be modified by Clause 19.3 in specified events of termination), 8 (Records and Auditing), 9.2 (Pharmacovigilance), 10 (Confidentiality), 11.1 and 11.2 (Intellectual Property), 15 (Indemnification), 16 (Limitation of Liability), 17 (Term and Survival), 19 (Effect of Termination), 20 (Dispute Resolution) and 21 (Miscellaneous).

18. **Termination**

18.1 **Licensee termination for convenience**

The Licensee may terminate this Agreement at any time for any reason by giving ninety (90) days' prior written notice to Ascendis.

18.2 **Right to Terminate for Material Breach**

(a) In the event that Ascendis commits a material breach of any of the terms of this Agreement on its part to be performed or observed, Licensee shall have the right to terminate this Agreement, in whole or in part, by giving sixty (60) days' written notice to Ascendis; provided, however, that in the case of a material breach capable of being remedied, if Ascendis shall remedy such material breach within sixty (60) days after the notice has been given, then the notice shall not be effective and the Agreement shall not terminate.

(b) In the event that Licensee commits a material breach of any of the material obligations under Section 2.3, 7.1, 7.2 or 10 and such material breach causes material loss by Ascendis that exceeds [***] dollars ($[***]), Ascendis shall have the right to terminate this Agreement, in whole or in part, by giving ninety (90) days' written notice to Licensee; provided, however, that if Licensee shall remedy such material breach or reduce such loss below [***] dollars ($[***]) within ninety (90) days after the notice has been given, then the notice shall not be effective and the Agreement shall not terminate.

18.3 **Right to Terminate for Bankruptcy**

(A) **Right to terminate**

A Party (the "Non-Bankrupt Party") may, to the extent legally permissible and in addition to any other remedies available to it by law or in equity, terminate this Agreement, as a whole by notice to the other Party (the "Bankrupt Party"), in the event the Bankrupt Party has become bankrupt, has made an assignment for the benefit of its creditors or there has been appointed a trustee or receiver of the Bankrupt Party for all or a substantial part of its property or any case or proceeding

shall have been commenced or other action taken by or against the Bankrupt Party in bankruptcy or seeking reorganisation, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganisation or other similar act or law of any jurisdiction now or hereafter in effect and any such event shall have continued for sixty (60) days undismissed, unbonded and undischarged.

(B) **Retention of rights upon Bankruptcy**

In the event of a bankruptcy of the Bankrupt Party, the rights and licences granted under or pursuant to this Agreement by the Bankrupt Party to the Non-Bankrupt Party are, and shall otherwise be deemed to be, for purposes of paragraph 365(n) of the United States Bankruptcy Code, licences of rights to "intellectual property" as defined under paragraph 101(35A) of the United States Bankruptcy Code. The Parties agree that the Non-Bankrupt Party, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code. The Parties further agree that in the event of the commencement of a bankruptcy proceeding by or against the Bankrupt Party, including under the United States Bankruptcy Code, the Non-Bankrupt Party shall, to the extent legally permissible, be entitled to complete access to any such intellectual property of the Bankrupt Party that pertains to the rights granted in the licenses under this Agreement and embodiments of such intellectual property.

18.4 **Ascendis termination for Change of Control.** Ascendis may terminate this Agreement as a whole, [***] written notice to Licensee, in the event of a Change of Control in favour of a Competitor.

18.5 **Ascendis termination for Patent challenge.**

(A) Without limiting Clause 18.5(B), [***], Ascendis may terminate this Agreement as a whole effective upon thirty (30)-day written notice to the Licensee, if the Licensee or its Affiliates challenges [***] in a court the validity, [***] of any Ascendis Patent and such challenge is not withdrawn within such thirty (30)-day period, unless Ascendis or its Affiliates or any of its licensees has [***].

(B) At any time during the Term, Ascendis may terminate this Agreement as a whole effective upon thirty (30)-day written notice to the Licensee, if the Licensee or its Affiliates challenges [***] in a court the validity, [***] of any (i) Ascendis Patent [***] or (ii) any Ascendis Patent [***], and in either case of (i) or (ii), such challenge is not withdrawn within such thirty (30)-day period, unless Ascendis or its Affiliates or any of its licensees has [***].

19. **Effect of Termination**

19.1 The termination of this Agreement shall be without prejudice to:

(A) the obligation of the Licensee to pay to Ascendis all sums accrued, due and payable under Clause 7 as of the effective date of termination; and

(B) any right of, or remedy available to, either Party against the other in respect of any action or omission hereunder prior to such termination.

19.2 **Termination by the Licensee**

(A) **For Convenience**

In the event of termination of this Agreement in whole or in part by the Licensee pursuant to Clause 18.1:

(1) the licences granted to Ascendis and its Affiliates under Clause 2.2 shall [***], except that [***], and [***];

(2) Licensee shall transfer, or cause to be transferred, all [***] existing as of the effective date of such termination to Ascendis or its designee, [***], and Ascendis shall [***];

(3) the licences granted to the Licensee under Clause 2.1 shall terminate as of the effective date of such termination;

(4) [***]; and

(5) obligations under Clause 2.3 shall cease for both Parties and their Affiliates.

(B) **For Ascendis' breach or bankruptcy**

In the event of termination of this Agreement in whole by the Licensee pursuant to Clauses 0 or 18.3(A), subject to Clause 19.5:

(1) the licence granted to the Licensee under Clause 2.1 (and all sublicenses granted thereunder) shall survive (along with all obligations associated therewith) in respect of any Ascendis Patents, Ascendis Technical Information, Ascendis Program IP and Ascendis' and its Affiliates' interest in Joint Program IP that exist as of the effective date of such termination;

(2) the licence granted to Ascendis and its Affiliates under Clause 2.2 shall survive (along with all obligations associated therewith), in respect of the Licensee's and its Affiliates' interest in any Joint Program IP and Licensee Program IP that exist as of the effective date of such termination;

(3) [***];

(4) if the effective date of such termination is prior to the [***] anniversary of the Effective Date, unless otherwise agreed to by the Licensee, Ascendis' obligations under Clause 5.1 shall survive until the [***] anniversary of the Effective Date; and

(5) Ascendis' and its Affiliates' obligations under Clause 2.3(A) shall survive until the [***] anniversary of the effective date of such termination.

19.3 **Termination by Ascendis**

In the event of termination of this Agreement in whole or in part by Ascendis pursuant to Clauses 18.2, 18.3, 18.4 or 18.5, subject to Clause 19.4:

(A) the licence granted to Ascendis and its Affiliates under Clause 2.2 shall [***], except that [***], and Ascendis [***];

(B) Licensee shall transfer, or cause to be transferred, [***] existing as of the effective date of such termination to Ascendis or its designee, [***], and Ascendis shall [***];

(C) [***];

(D) obligations under Clause 2.3 shall cease for both Parties and their Affiliates; and

(E) the licence granted to the Licensee under Clause 2.1 shall terminate as of the effective date of the termination.

19.4 **Inventory at termination**

In the event this Agreement is terminated for any reason, the Licensee shall have the right to sell or otherwise dispose of Licensed Product then in its stock for up to [***] ([***]) months following the termination of this Agreement.

19.5 **Continuation of sub-licences**

Upon termination of this Agreement, any existing, permitted sub-licence granted by a Party under this Agreement shall continue in full force and effect, provided that the permitted Sub-Licensee did not cause the breach that gave rise to a termination under Clause 18.2 and agrees to be bound by all the terms and conditions of this Agreement that are applicable to such permitted Sub-Licensee, including, without limitation, rendering directly to the licensing Party all payments and other obligations due to the licensing Party related to such sub-licence.

19.6 **Return of Confidential Information**

Following any expiration or termination of this Agreement, the Party that has Confidential Information of the other Party shall return to the other Party (or destroy at such Party's written request) all such Confidential Information in its possession as of the effective date of expiration or termination (with the exception of one copy of such Confidential Information, which may be retained by the legal department of the Party that received such Confidential Information to confirm compliance with the non-use and non-disclosure provisions of this Agreement, and any Confidential Information of the other Party contained in its laboratory notebooks or databases.

20. **Dispute Resolution**

20.1 **Internal resolution**

(A) Any dispute, controversy or claim related to matters within the powers and authority of the JDC shall be resolved by the Parties in accordance with procedures set forth in Clause 4.6.

(B) Except as otherwise expressly provided herein, including in Clause 20.1(A) above, in the event of any controversy, claim or other dispute arising out of or relating to compliance with this Agreement, or the validity, breach, termination or interpretation of this Agreement, such dispute shall be first referred to the Executives for resolution, prior to proceeding under the following provisions of Clause 20.2. A dispute shall be referred to the Executives upon one Party providing the other Party with written notice that such dispute exists, and the Executives shall attempt to resolve such dispute through good faith discussions. In the event that the Executives cannot resolve such dispute within [***] ([***]) days of such other Party's receipt of such

written notice, either Party may initiate the dispute resolution procedures set forth in Clause 20.2. The Parties agree that any discussions between such Executives, or their designees, regarding such dispute shall be the Confidential Information of both Parties and do not constitute settlement discussions, unless the Parties agree otherwise in writing.

20.2 **Arbitration**

Except as otherwise expressly provided in this Agreement, including but not limited to Clause 20.3, the Parties agree that any dispute not resolved internally by the Parties pursuant to Clause 20.1(B), shall be resolved through binding arbitration conducted under the auspices of the [***] (for purposes of this Clause 20.2, the "Rules"), except as modified in this Agreement, applying the substantive law specified in Clause 21.12 (Governing law). A Party may initiate arbitration by written notice to the other Party of its intention to arbitrate, and such demand notice shall specify in reasonable detail the nature of the dispute. Each Party shall select one (1) arbitrator, and the two (2) arbitrators so selected shall choose a third arbitrator. All three (3) arbitrators shall serve as neutrals and have at least [***] ([***]) years of: (a) dispute resolution experience (including judicial experience); and/or (b) legal or business experience in the biotech or pharmaceutical industry. In any event, at least one (1) arbitrator shall satisfy the foregoing experience requirement under Clause 20.2(b). Notwithstanding anything to the contrary in this Clause 20.2, in the event of a dispute regarding the Prosecution and Maintenance activities described in Clause 12 at least one (1) arbitrator shall have expertise in patent law. If a Party fails to nominate its arbitrator, or if the Parties' arbitrators cannot agree on the third arbitrator, the necessary appointments shall be made in accordance with the Rules. Once appointed by a Party, such Party shall have no *ex parte* communication with its appointed arbitrator. The arbitration proceedings shall be conducted in [***]. The arbitration proceedings and all pleadings and written evidence shall be in the English language. Any written evidence originally in another language shall be submitted in English translation accompanied by the original or a true copy thereof. Each Party agrees to use commercially reasonable efforts to make all of its current employees available, if reasonably needed, and agrees that the arbitrators may deem any party as "necessary." The arbitrators shall be instructed and required to render a written, binding, non-appealable resolution and award on each issue that clearly states the basis upon which such resolution and award is made. The written resolution and award shall be delivered to the Parties as expeditiously as possible, but in no event more than [***] ([***]) days after conclusion of the hearing, unless otherwise agreed by the Parties. Judgment upon such award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such an award and order for enforcement. [***] The Parties may apply to any court of competent jurisdiction for a temporary restraining order, preliminary injunction or other interim or conservatory relief, as necessary, without breaching these arbitration provisions and without abridging the powers of the arbitrators. At the request of either Party, the arbitrators shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings. The arbitrators shall have the power to decide all questions of arbitrability. The Parties agree that: (i) they shall share equally the fees and expenses of the arbitrators; and (ii) each Party shall bear its own attorneys' fees and associated costs and expenses.

20.3 **Patent validity**

Notwithstanding the other provisions of this Clause 20, any dispute that involves the validity, infringement or claim interpretation of a Patent that is issued: (a) in the United States shall be subject to actions before the United States Patent and Trademark Office and/or submitted exclusively to the federal court located in the jurisdiction of the district where any

of the defendants resides; and (b) in any other country shall be brought before an appropriate regulatory or administrative body or court in that country, and the Parties hereby consent to the jurisdiction and venue of such courts and bodies. For the sake of clarity, such Patent disputes shall not be subject to the provisions of Clause 20.2. Nothing in this Agreement shall be construed to prevent the Licensee from disputing or challenging the validity of a Third Party's Patent.

21. Miscellaneous

21.1 General assurances

At any time after the date hereof each of the Parties shall, at the request and cost of the other Party, execute or procure the execution of such documents and perform or procure the performance of such acts as the other Party may reasonably require for the purpose of giving to the other Party the full benefit of all the provisions of this Agreement, subject to any express restrictions in this Agreement on the extent of either Party's obligations under this Agreement. This includes in particular (without prejudice to the generality of the foregoing) entry into forms of licence or other instruments confirming such rights for registration with appropriate Intellectual Property Offices (including in the form set out in Schedule 4), Regulatory Authorities and other authorities in the Territory.

21.2 Unenforceability and severability

If any of the provisions of this Agreement are held to be void or unenforceable, then such void or unenforceable provisions shall be replaced by valid and enforceable provisions that will achieve as far as possible the economic business intentions of the Parties. However, the remainder of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e. the Parties would presumably have concluded this Agreement without the unenforceable provisions.

21.3 Assignments

Neither this Agreement nor any of the rights and obligations created herein is assignable or transferable by either Party without the prior written consent of the other, such consent not to be unreasonably withheld or delayed.

Notwithstanding the preceding sentence, each Party is entitled to assign this Agreement and any rights created herein to, subject to the assumption of the obligations herein by, any Affiliate of such Party or any purchaser of the whole or a substantial part of the business of such Party. For the avoidance of doubt, the Parties agree that the Ascendis Platform Technology constitutes a substantial part of the business of Ascendis.

21.4 Rights cumulative and other matters

(A) The rights, powers, privileges and remedies provided in this Agreement are cumulative and are not exclusive of any rights, powers, privileges or remedies provided by law or otherwise.

(B) No failure to exercise nor any delay in exercising by any Party to this Agreement of any right, power, privilege or remedy under this Agreement shall impair or operate as a waiver thereof in whole or in part.

(C) No single or partial exercise of any right, power privilege or remedy under this Agreement shall prevent any further or other exercise thereof or the exercise of any other right, powers, privilege or remedy.

21.5 **Costs of preparation**

The Parties hereto shall pay their own respective legal costs incurred in the preparation of this Agreement.

21.6 **Entire Agreement and variation**

(A) This Agreement, together with any documents referred to in it, constitutes the whole agreement between the Parties relating to its subject matter and supersedes and extinguishes any prior drafts, agreements, undertakings, representations, warranties and arrangements of any nature, whether in writing or oral, relating to such subject matter. All information related to the subject matter of this Agreement previously exchanged shall be protected under Clause 10 of this Agreement as if disclosed under this Agreement.

(B) Each Party acknowledges that it has not been induced to enter into this Agreement by any representation or warranty other than those contained in this Agreement and, having negotiated and freely entered into this Agreement, agrees that it shall have no remedy in respect of any other such representation or warranty except in the case of fraud.

(C) No variation of this Agreement shall be effective unless made in writing and signed by each of the Parties.

21.7 **Notices and invoices**

(A) Any notice (which term shall in this Clause 21.7 include any communication) required to be given under this Agreement or in connection with the matters contemplated by it shall, except where otherwise specifically provided, be in writing in the English language.

(B) Any such notice shall be addressed as provided in Clause 21.7(C) and may be:

(1) personally delivered, in which case it shall be deemed to have been given upon delivery at the relevant address if it is delivered not later than 17.00 hours on a Business Day, or, if it is delivered later than 17.00 hours on a Business Day or at any time on a day which is not a Business Day, at 08.00 hours on the next Business Day;

(2) sent by pre-paid registered airmail, or by air courier in which case it shall be deemed to have been given seven (7) Business Days after the date of posting in the case of registered airmail or two (2) Business Days after delivery to the courier, in the case of air courier;

(3) sent by electronic mail, in which case it shall be deemed to have been given when sent from the electronic mail exchange, provided that any notice sent by electronic mail after 17.00 hours on any Business Day or at any time on a day which is not a Business Day shall be deemed to have been given at 08.00 on the next Business Day.

(C) The addresses and other details of the Parties referred to in this Clause 21.7(C) are, subject to Clause 21.7(D):

Ascendis' address:

Ascendis Pharma Endocrinology Division A/S
Tuborg Boulevard 5
DK-2900 Hellerup
Denmark

Email: [***]
Attention: [***]

VISEN Pharmaceuticals's address:

VISEN Pharmaceuticals
P.O. Box 472
2nd Floor, Harbour Place
103 South Church Street
George Town, Grand Cayman KY1-1106
Cayman Islands

Email: [***]
Attention: [***]

(D) Either Party to this Agreement may notify the other Party of any change to the address or any of the other details specified in Clause 21.7, provided that such notification shall only be effective on the date specified in such notice or five (5) Business Days after the notice is given, whichever is later.

(E) **Invoices**

All invoices that are required or permitted under this Agreement shall be in writing and sent by Ascendis to the Licensee at the address provided under Clause 21.7(C).

21.8 **Force Majeure**

Neither Party to this Agreement shall be deemed to be in breach of this Agreement or otherwise liable to the other as a result of any delay or failure in the performance of its obligations under this Agreement if and to the extent that such delay or failure is caused by Force Majeure, and the time for performance of the relevant obligation(s) shall be extended accordingly. The Party concerned shall promptly notify the other Party of the nature and effect of such event and both Parties shall, where the same is practicable, use Diligent Efforts to minimise such effect and to comply with the respective obligations herein contained as nearly as may be in their original form, provided that if the Force Majeure event continues for a period of ninety (90) days or more following notification, the Party not affected by the event may terminate this Agreement by giving not less than thirty (30) days prior notice to the other Party.

21.9 **Relationship of the Parties**

(A) Nothing in this Agreement shall constitute, or be deemed to constitute, a partnership between the Parties nor, except as expressly provided, shall it constitute, or be deemed to constitute, any Party the agent of any other Party for any purpose.

(B) Subject to any express provisions to the contrary in this Agreement, neither Party shall have any right or authority to and shall not do any act, enter into any contract, make any representation, give any warranty, incur any liability, assume any obligation, whether express or implied, of any kind on behalf of the other Party or bind the other Party in any way.

21.10 **Counterparts**

This Agreement may be executed in any number of counterparts, which shall together constitute one Agreement. Any Party may enter into this Agreement by signing any such counterpart.

21.11 **Third Party rights**

No person who is not a party to this Agreement shall have any right to enforce any term of this Agreement.

21.12 **Governing law**

This Agreement shall be governed by and construed in accordance with the laws of the state of Delaware, USA, without reference to its conflict of laws principles, and shall not be governed by the United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention).

[Signature page follows]

AS WITNESS the Parties hereof have executed this Agreement the day and year first before written.

Signed by	) /s/ Michael Wolff Jensen, Chairman
for and on behalf of	) /s/ Jan Mikkelsen, CEO
ASCENDIS PHARMA	)
ENDOCRINOLOGY DIVISION A/S	)
Signed by	) [***]
for and on behalf of	)
VISEN PHARMACEUTICALS	)

SCHEDULE 1 : ASCENDIS PATENTS

[***]

SCHEDULE 2 : ASCENDIS TECHNICAL INFORMATION

1.1 [***]

SCHEDULE 3 : EXCLUDED INDICATIONS

[***]

SCHEDULE 4 : SHORT FORM PATENT LICENCE

THIS AGREEMENT is made the [ ] day of [ ]

BETWEEN:

(1) **ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S**, ("Ascendis"), a company registered in Denmark with its registered office at Tuborg Boulevard 5, DK-2900 Hellerup, Denmark; and

(2) **VISEN PHARMACEUTICALS**, a company registered under the laws of the Cayman Islands with its registered address at P.O. Box 472, 2nd Floor, Harbour Place, 103 South Church Street, George Town, Grand Cayman KY1-1106, Cayman Islands.

Ascendis and the Licensee are each a "Party", and together the "Parties", to this agreement.

Ascendis hereby grants to the Licensee an exclusive licence for exploitation of the patent(s) set out in the Appendix below worldwide for the treatment and/or prevention of any disease, condition or disorder of the eye and adnexa, defined according to WHO ICD (but non-exclusive for Diabetic Retinopathy), subject to and terminable in accordance with the terms and conditions of an agreement between the Parties hereto dated [ ].

Appendix

[insert details of relevant patents/patent applications]

AS WITNESS the Parties have executed this agreement the day and year first above written.

Signed by	)
for and on behalf of	)
ASCENDIS PHARMA	)
ENDOCRINOLOGY DIVISION A/S	)

Signed by	)
for and on behalf of	)
VISEN PHARMACEUTICALS	)

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

EXECUTION VERSION
CONFIDENTIAL

Exclusive Licence Agreement

between

Ascendis Pharma Bone Diseases A/S

as the Licensor or Ascendis on the one hand

and

VISEN PHARMACEUTICALS

as the Licensee on the other hand

CONTENTS

THIS EXCLUSIVE LICENCE AGREEMENT (the "Agreement") is dated November 7, 2018 and made

BETWEEN:

(1) **ASCENDIS PHARMA BONE DISEASES A/S**, ("Licensor" or "Ascendis"), a company registered in Denmark with its registered office at Tuborg Boulevard 5, DK-2900 Hellerup, Denmark;

(2) **VISEN PHARMACEUTICALS**, ("Licensee"), a company established under the laws of the Cayman Islands with its registered address at P.O. Box 472, 2nd Floor, Harbour Place, 103 South Church Street, George Town, Grand Cayman KY1-1106, Cayman Islands.

Ascendis and the Licensee are each a "Party", and together the "Parties", to this Agreement.

Background:

(A) Ascendis and its Affiliates Control proprietary rights, titles and interests in patents and technical information relating to Licensed Products (as defined below) within the area of bone disorders.

(B) The Licensee wishes to develop and to commercialise such Licensed Products in the Field in the Territory (such terms defined below), and Ascendis wishes to grant the Licensee an exclusive licence under certain patents, technical information and other intellectual property to develop and commercialise such Licensed Products in the Field in the Territory, on the terms and conditions of this Agreement.

THE PARTIES AGREE THAT:

1. **Interpretation**

1.1 **Definitions**

"Accounting Standard" means, with respect to the Licensee, either: (a) International Financial Reporting Standards ("IFRS"); or (b) United States generally accepted accounting principles ("GAAP"), in either case, which standards or principles (as applicable) are currently used at the applicable time, and as consistently applied, by the Licensee.

"Affiliate" means any business Entity which from time-to-time controls, is controlled by or is under common control with a Party to this Agreement, in each case only for so long as such control exists. As used in this definition, "control" of an Entity means the beneficial ownership (either directly or indirectly) of more than fifty percent (50%) of the total voting power of the shares or securities then outstanding normally entitled to vote in elections of the board of directors or other managing authority of such Entity. For the avoidance of doubt, neither Licensee nor any of its subsidiaries shall be considered as an Affiliate of Ascendis and an Affiliate of Ascendis shall not be considered as an Affiliate of either Licensee or its subsidiaries for the purposes of this Agreement.

"Applicable Laws" means all laws, statutes, codes, ordinances, rules and regulations that have been enacted (including without limitation by a Regulatory Authority) in any jurisdiction in the Territory and which are in force as of the Effective Date or come into force during the term of this Agreement and that are applicable to the research, development, Manufacture, or commercialization of Licensed Product or the activities of the Parties under this Agreement, including, without limitation: (a) applicable regulations and guidelines of the NMPA and other Regulatory Authorities and the ICH guidelines; (b) applicable Good Clinical Practices, Good Laboratory Practices and Good Manufacturing Practices promulgated by the NMPA and other Regulatory Authorities or the ICH; and (c) all applicable industry and trade standards, including the applicable standards of the ISO with, at a minimum, the ISO 9001/9002 quality standards.

"Ascendis FTE Costs" means, for all activities performed by Ascendis or its Affiliates in accordance with the Research and Technical Development Plan or as otherwise directed in writing by the Licensee and agreed to by Ascendis or its Affiliates, the product of: (a) the number of FTEs used by Ascendis or its Affiliates for such activities as set forth in a Research and Technical Development Plan or other written document approved by the Licensee; and (b) the Ascendis FTE Rate. For the avoidance of doubt, the costs of approved service providers fulfilling the obligations of Ascendis or its Affiliates in performing such activities are covered separately under subsection (A) of the "Research and Technical Development Plan Expenses" definition, and are not a part of the Ascendis FTE Costs.

"Ascendis FTE Rate" means (a) if, at the time the applicable Ascendis FTE Costs are incurred, Ascendis owns [***] percent ([***]%) or more of all outstanding preferred shares of Licensee, [***] Euros (€ [***]) per FTE, and (b) if, at the time the applicable Ascendis FTE Costs are incurred, Ascendis owns less than [***] percent ([***]%) of outstanding preferred shares of Licensee, [***] Euros (€ [***]) per FTE; provided in each case of (a) and (b), such amount is fully burdened and includes without limitation, for each FTE, [***], utilities, [***], and a pro rata allocation of general and administrative expenses.

"Ascendis Program IP" means: any Program IP conceived or generated solely by employees, agents or service providers of Ascendis or its Affiliates.

"Ascendis Indemnitee" has the meaning ascribed to it in Clause 15.1.

"Ascendis Patents" means: (a) the patents and patent applications listed in Schedule 1 as of the Effective Date and any conversion, continuation, continuation-in-part, division, provisional or substitution thereof, and any patents issuing thereon, any reissues, re-examinations, confirmations or extensions of such patents (including supplementary protection certificates) and any foreign counterparts of such patent applications and patents in any country in the Territory; and (b) any and all other Patents that are Controlled by Ascendis or its Affiliates as of the Effective Date or at any time thereafter during the term of this Agreement (including without limitation Patents within the Ascendis Program IP or Joint Program IP) that are necessary or useful to make, have made, use, sell, offer for sale or import a Licensed Product.

"Ascendis Technical Information" means: (a) the Technical Information listed in Schedule 2 as of the Effective Date; and (b) any and all other Technical Information that is Controlled by Ascendis or its Affiliates, as of the Effective Date or at any time thereafter during the term of this Agreement (including without limitation Technical Information within the Ascendis Program IP or Joint Program IP), that is necessary or useful to make, have made, use, sell, offer for sale or import a Licensed Product.

"Ascendis Platform Technology" means, as of the Effective Date or at any time thereafter during the term of this Agreement, Ascendis' proprietary chemistry, materials and methodologies for [***] a substrate of interest (e.g., [***]) to various carriers (including [***]) *via* a TransCon Linker, [***].

"Bankrupt Party" has the meaning ascribed to it in Clause 18.3(A).

"Business Day" means a day (other than a Saturday or Sunday) on which banks are open for ordinary face to face banking business in Copenhagen (Denmark), Cayman, China, and San Francisco (California, USA).

"Change of Control" means the occurrence of any of the following events: (a) any Competitor takes control (as the term "control" is defined in the definition of "Affiliate") of Licensee; or (b) Licensee: (i) consolidates with, or merges with or into, a Competitor; or (ii) transfers all or substantially all of its assets to any Competitor.

"Competitor" means a Third Party that [***] commercializing (i.e., as the party having the proprietary rights to and booking sales for, but not as a distributor or wholesaler of) a [***] in [***] as of the date of a Change of Control.

"Confidential Information" means confidential Technical Information (of whatever kind and in whatever form or medium, including copies thereof): (a) disclosed by or on behalf of a Party in connection with this Agreement, whether prior to or during the term of this Agreement and whether disclosed orally, electronically, by observation or in writing; and/or (b) created by, or on behalf of, either Party, or created jointly by the Parties, in the course of this Agreement. "Confidential Information" includes confidential Technical Information regarding such Party's research, development plans, clinical trial designs, preclinical and clinical data, technology, products, business information or objectives and other information of the type that is customarily considered to be confidential information by Parties engaged in activities that are substantially similar to the activities being engaged in by the Parties pursuant to this Agreement. The following shall be deemed the Confidential Information of the Licensee: any and all financial or product pipeline information related to the Licensee provided to Ascendis (whether provided by the Licensee itself or through a Third Party), as well as Licensee Program IP, and the Research and Technical Development Plans. The following shall be deemed the Confidential Information of Ascendis: Ascendis Platform Technology, Ascendis Technical Information, Ascendis Program IP and Ascendis Patents. The following shall be deemed the Confidential Information of both Parties: the terms and conditions of this Agreement.

"Control" or "Controlled" means, with respect to an item of information or Intellectual Property, that a Party has the right, power and legal authority, whether arising by ownership, licence or other authorisation, to disclose, and/or to grant and authorise licences or sub-licences under, such items as required under the terms of this Agreement, without violating the terms of any written agreement with any Third Party under which such Party or its Affiliates first acquired such rights to such item of information or Intellectual Property.

"Diligent Efforts" means with respect to a Party's research, development, and commercialisation of Licensed Products, the level of efforts and resources such Party would typically exert in similar circumstances pursuing the development and commercialisation of a similar product with similar market potential taking into account the stage of development or commercialisation, market potential and market size, the product life cycle, the risk of development or commercialisation of the Licensed Product, the cost effectiveness of efforts or resources, the competitiveness of alternative products that are or are expected to be in the marketplace, the scope and duration of patent rights or other proprietary rights related to the Licensed Product, and the profitability of the Licensed Product [***]. The efforts and resources of each Party's respective Affiliates and Sub-Licensees shall count towards that Party's own Diligent Efforts. Notwithstanding the foregoing, the exercise of diligence by the Licensee shall be determined by judging the Licensee's commercially reasonable efforts taken as a whole[***].

"Effective Date" means the date of this Agreement.

"Endocrinology Disorders" means [***]

"Endocrinology Product" means a product consisting of a substrate of interest (e.g., [***] to a carrier of interest (including [***]) via a TransCon Linker for the treatment of Endocrinology Disorders; provided, that [***]

"Entity" means, and includes, any person, firm or company or group of persons or unincorporated body.

"Excluded Indications" means the indications specified in Schedule 3.

"Executives" means the Chief Executive Officer at the Licensee and the Chief Executive Officer at Ascendis.

"FDA" means the US Food and Drug Administration or any successor agency with comparable responsibilities.

"Field" means the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the Excluded Indications.

"Force Majeure" means any circumstances not within the reasonable control of the Party concerned including, without limitation: (a) any strike, lockout or other industrial action, or any shortage of or difficulty in obtaining labour, fuel, raw materials or components; (b) any destruction, temporary or permanent breakdown, malfunction or damage of or to any premises, plant, equipment (including computer systems) or materials; (c) any breach of contract, default or insolvency by or of any Third Party, other than an Affiliate of the Party affected by the force majeure, or an employee or officer of that Party or Affiliate; (d) any action taken by a governmental or public authority imposing an embargo, export or import restriction, rationing, quota or other restriction or prohibition; (e) any civil commotion or disorder, riot, invasion, war, threat of or preparation for war; or (f) any accident, fire, or explosion, (other than in each case, one caused by a breach of contract by or assistance of the Party concerned) storm, flood, earthquake, subsidence, epidemic or other natural physical disaster. Notwithstanding the foregoing, lack of funds, manpower or equipment, interruption or failure of utility service and the fault or misconduct by any personnel engaged by a Party shall not be an event of Force Majeure.

"FTE" means a full time equivalent person year of work (consisting of [***]), prorated on a daily or hourly basis as necessary.

"Good Clinical Practice" means the applicable principles and guidelines for good clinical practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation those set out in the Harmonised Tripartite Guideline for Good Clinical Practice as finalised by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"Good Distribution Practice" means the applicable principles and guidelines for good distribution practice of drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation those set out in Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use, based on Article 84 and Article 85b(3) of Directive 2001/83/EC.

"Good Laboratory Practice" means the applicable principles and guidelines for good laboratory practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation those set out in the OECD Principles of Good Laboratory Practice published by the Organisation for Economic Co-Operation and Development.

"Good Manufacturing Practice" means all applicable principles and guidelines for good manufacturing practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation as specified in the applicable provisions of (i) European Directive 2003/94/EC and further guidance as published by the European Commission in Volume IV of "The rules governing medicinal products in the European Community" and (ii) Title 21 Parts 210 and 211 of the US Code of Federal Regulations (21 CFR, parts 210 and 211).

"ICH" means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"Indemnified Party" has the meaning ascribed to it in Clause 15.3.

"Injector" means any device developed by Ascendis for the purpose of administering TransCon PTH.

"Intellectual Property" means registered or unregistered trademarks, Patents, registered designs, unregistered design rights, business, company, domain or product names, service marks, copyright, know-how, Confidential Information, database rights, any rights in clinical study results, applications for and the right to apply for any of the foregoing, and any similar or analogous rights anywhere in the Territory.

"Intellectual Property Office" means the official local patent, trade mark or other Intellectual Property registry in each part of the Territory responsible for granting, maintaining records of, Patents, trademarks or other Intellectual Property and any instruments made in respect thereof.

"ISO" means the International Organization for Standardization.

"Joint Development Committee" or "JDC" means the joint development committee established under Clause 4.6.

"Joint Program IP" means any Program IP conceived or generated during the course of, and in connection with, this Agreement by employees, agents or service providers of both Ascendis and the Licensee or their respective Affiliates or Sub-Licensees.

"Licensed Product" means a product consisting of parathyroid hormone (1-34) (PTH) [***] to a carrier [***] by a TransCon Linker and which is developed utilizing the Ascendis Platform Technology, regardless of its finished form, formulation or dosage, alone (the foregoing alone, "TransCon PTH") and, if Ascendis has developed an Injector for use in a clinical trial outside the Territory, also including the Injector.

"Licensed Product Patents" means all Ascendis Patents that claim [***] a Licensed Product in the form as which is concurrently being developed or commercialised, as applicable, by or on behalf of Ascendis or its Affiliates outside of the Territory.

"Licensee Program IP" means: any Program IP conceived or generated solely by employees, agents or service providers of the Licensee or its Affiliates.

"Licensee Indemnitee" has the meaning ascribed to it in Clause 15.2.

"Long-Acting Product" is a product that is intended to be administered to a subject once a day or less frequently than once a day.

"Loss" or "Losses" means any and all losses, liabilities, damages, fines, penalties, costs or expense (including reasonable attorneys' fees and other expenses of litigation).

"Manufacture" or "Manufacturing" means any manufacturing activity of any Licensed Product, or any ingredient thereof, including manufacturing for pre-clinical or clinical use, or commercial sale, testing, handling, packaging and storage, ongoing stability tests and regulatory activities related to any of the foregoing.

"NMPA" means the National Medical Product Administrations of the People's Republic of China, or any successor agency with comparable responsibilities.

"Non-Bankrupt Party" has the meaning ascribed to it in Clause 18.3(A).

"Patents" means any and all: (a) issued patents, including inventor's certificates; (b) patent applications, including any conversion, continuation, continuation-in-part, division, provisional or substitution thereof, and any patents issuing thereon; (c) any reissues, re-examinations, confirmations or extensions of such patents (including supplementary protection certificates); and (d) any foreign counterparts of such patent applications and patents in any country in the Territory.

"Program IP" means any data, results (including all clinical data), improvements and inventions generated by or on behalf of Ascendis or Licensee, or the Parties jointly, in connection with the research, development, Manufacturing, or commercialization activities conducted with respect to the Licensed Product under this Agreement, and all Intellectual Property therein.

"Quarterly Period" means each period of three months commencing on 01 January, 01 April, 01 July and 01 October in a given calendar year.

"Regulatory Approval" means any and all approvals, licenses, registrations, or authorizations of any country, federal, supranational, state, or local regulatory agency, department, bureau, or other government entity that are necessary for the commercialisation of any Licensed Product in a given jurisdiction.

"Regulatory Authority" means any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in any jurisdiction in the Territory involved in the granting of Regulatory Approval for, or involved in the regulation of, pharmaceutical products.

"Research and Technical Development Plan" has the meaning ascribed to it in Clause 4.1.

"Research and Technical Development Plan Activities" means the Research and Technical Development Plan Activities allocated to Ascendis or its Affiliates as set forth in a Research and Technical Development Plan.

"Research and Technical Development Plan Expenses" means the following costs and expenses actually incurred by Ascendis or its Affiliates after the Effective Date in carrying out the Ascendis Research and Technical Development Plan Activities:

(A) the out-of-pocket costs incurred by Ascendis or its Affiliates of having the Research and Technical Development Plan Activities performed by approved service providers (including without limitation Third Party manufacturing organisations) in accordance with the applicable Research and Technical Development Plan;

(B) Ascendis FTE Costs; and

(C) any other costs or expenses specifically identified and included in the applicable Research and Technical Development Plan, which, for the avoidance of doubt, may include, without limitation, pre-paid amounts.

"Share Purchase Agreement" shall mean that certain Share Purchase Agreement dated as of even date herewith, by and among Licensee, Ascendis-China Ltd., Ascendis Pharma A/S, Vivo Plenilune IX Limited, and Sofinnova Venture Partners IX, L.P.

"Shareholders Agreement" means that certain Shareholders Agreement dated as of even date herewith, by and among Licensee, Ascendis-China Ltd., Ascendis Pharma A/S, Vivo Plenilune IX Limited, and Sofinnova Venture Partners IX, L.P.

"SDEA" has the meaning ascribed to it in Clause 9.1.

"Sub-Licensee" means any Entity that has been granted a sub-licence by either Party of its rights granted hereunder in accordance with Clause 2.4.

"Technical Information" means any and all: (a) identifiable know-how, data, inventions, discoveries, findings, methods, proprietary information, processes, techniques, materials and other information and technology (whether patentable or not) including formulae, biological materials, practices, test data (including pharmacological, toxicological and clinical information and related reports, statistical analyses, expert opinions and the like), analytical and quality control data, marketing, pricing, distribution, cost and sales data or descriptions; and (b) all Intellectual Property with respect to the items in subsection (a) above other than Patents. For clarity, as used in this Agreement, the term "Technical Information" excludes Patents.

"Territory" means the People's Republic of China, including Hong Kong, Macao and Taiwan.

"Third Party" means any Entity other than Ascendis or its Affiliates or its Sub-Licensees, or the Licensee or its Affiliates or its Sub-Licensees.

"Third Party Claim" means any action, suit or other proceedings brought by a Third Party.

"TransCon Hydrogel" means Ascendis' proprietary [***] hydrogel containing TransCon Linkers

"TransCon Linker" means Ascendis' proprietary linker used in [***] a substrate of interest to various carriers (including [***], which chemical linker [***].

"TransCon [***]" means Ascendis' proprietary [***]-based carrier containing TransCon Linkers.

"Valid Claim" means any claim of a Patent that has not expired or been disclaimed, abandoned or dedicated to the public, or held revoked, unenforceable, unpatentable or invalid (whether through reexamination, reissue, opposition or otherwise) by a decision of a court or governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time frame allowed for appeal.

"VAT" means value added tax as provided for in the Value Added Tax Act 1994 and legislation supplemental thereto, TVA or any other system of value added tax as provided for in Council Directive 2006/112/EC applied in any Member State of the European Union and any other similar turnover, sales or purchase, tax or duty levied by any other jurisdiction whether central, regional or local.

1.2 **Construction**

In this Agreement where the context admits:

(A) references to any statute or statutory provisions shall be deemed to refer to those provisions as amended or re-enacted or as their application is modified by other provisions from time-to-time and any reference to a statutory provision shall include any subordinate legislation made from time-to-time under that provision;

(B) references to "this Agreement" or to any other agreement or document referred to in this Agreement mean this Agreement or such other agreement or document as may be amended, varied, supplemented, modified or novated from time-to-time, and include the Schedules;

(C) references to Clause(s) and Schedule(s) are references to clause(s) and schedule(s) of and to this Agreement, and each of the Schedules shall have effect as if set out in this Agreement;

(D) references to "proprietary" mean Controlled by a Party, but do not infer any requirement of a Patent;

(E) the headings and sub-headings in this Agreement are inserted for convenience only and shall not affect the construction of this Agreement;

(F) the singular includes the plural and vice versa, and references to the masculine, feminine and the neuter shall include all such genders;

(G) references to any Party include its successors and permitted assigns;

(H) the symbol "€" means the lawful currency of the member states of the European Union that adopt the single currency in accordance with the EC Treaty, known as the "Euro"; and

(I) the symbol "$" means the lawful currency of the United States of America, known as the "US Dollar".

2. **Grants and Restrictions**

2.1 Ascendis hereby grants to the Licensee an exclusive (even as to Ascendis, and subject to the terms and conditions of this Agreement), royalty-free (in accordance with Clause 7) licence (with the right to grant sub-licences subject to Clause 2.4) under Ascendis Patents and Ascendis Technical Information to develop, Manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize Licensed Product in the Field in the Territory. Licensee has the right to grant sublicenses (through one or more tiers) to its Affiliates that are operating companies for China, Hong Kong or other regions in the Territory and such sublicense agreements will be entered into each within [***] ([***]) days after the applicable operating company is incorporated and becomes operational (each such applicable operating company, a "Sublicensed Affiliate").

2.2 The Licensee hereby grants to Ascendis a non-exclusive, royalty-free, fully-paid, perpetual, irrevocable license (with the right to grant sub-licences subject to Clause 2.4) under the Licensee Program IP and Licensee's and its Affiliates' interest in Joint Program IP, in each case that are Controlled by the Licensee or its Affiliates, to make, have made, use, sell, offer for sale or import Licensed Products in any field of use outside the Territory. Ascendis will have the right to convert such non-exclusive license (in whole or in part, at Ascendis's discretion) to an exclusive license on commercial reasonable terms to be negotiated between the Parties in good faith.

2.3 **Restrictions**

(A) During the term of this Agreement, neither Ascendis nor its Affiliates shall conduct, or intentionally enable, or participate in, or license or otherwise authorize any Third Party to conduct, enable or participate in, the research, development, Manufacture or commercialisation of any Competing Product in the Territory (whether for its own account or for any Third Party). As used in this Clause 2.4, a "Competing Product" shall mean [***].

(B) During the term of this Agreement, the Licensee covenants that it shall not, and Licensee shall procure that its Affiliates and Sub-Licensees shall not, use or exploit the Ascendis Patents or Ascendis Technical Information otherwise than as expressly permitted under the licences granted to Licensee in Clause 2.1. Further, the Licensee shall not grant any license to any Third Party to Licensee's and its Affiliates interest in (i) Program IP [***] and (ii) any Program IP solely relating to the Ascendis Platform Technology [***], in each case of (i) and (ii), without the prior written consent of Ascendis.

2.4 Each Party agrees that:

(A) any and all sub-licences granted under Clauses 2.1 and 2.2 shall be on terms consistent with the terms of this Agreement, contain obligations on each Sub-Licensee to perform and observe terms and conditions similar to those contained herein so far as the same are applicable;

(B) it shall be liable to the other Party for any acts and omissions of its Sub-Licensee that cause any breach of the provisions of this Agreement; and

(C) it shall, within [***] ([***]) days of the grant of each sub-licence, provide the other Party with [***], provided that [***] from such sub-licence: [***].

2.5 Ascendis shall [***] not to commit any acts or omissions that could cause a material breach of any licence agreement pursuant to which Ascendis has rights to Intellectual Property that it has sub-licensed to the Licensee under this Agreement, such that its Third Party licensor terminates or amends such licence agreement in any way that materially adversely affects a licence or other right granted to the Licensee under this Agreement that is used in a Licensed Product being developed (including under an active Research and Technical Development Plan) or commercialised by the Licensee. Ascendis shall not exercise any rights it may have with respect to any such licence agreement, or amend, terminate, or waive any of its rights under such licence agreement in any way that materially adversely affects a licence or other right granted to the Licensee under this Agreement that is used in a Licensed Product being developed (including under an active Research and Technical Development Plan) or commercialised by the Licensee.

2.6 Only the licences granted or retained pursuant to the express terms of this Agreement shall be of any legal force or effect. No other licence rights shall be created by implication, estoppel or otherwise under this Agreement.

2.7 Each Party shall procure that its Affiliates shall comply with the terms and conditions of this Agreement and shall be liable to the other Party for any acts or omissions of such Affiliates which are not in compliance with the terms and conditions of this Agreement.

2.8 During the term of this Agreement, prior to engaging in substantive discussions with a Third Party regarding the license to such Third Party by Ascendis or its Affiliates under the Ascendis Platform Technology of [***] commercialise Endocrinology Product(s) in the Territory, either by license, option, or otherwise (a "ROFN Opportunity"), Ascendis shall notify Licensee thereof, except to the extent Ascendis cannot grant to Licensee or its Affiliates any rights to such Endocrinology Products in the Territory in light of restrictions imposed on Ascendis or its Affiliates under agreements by and between Ascendis or its Affiliates (on the one hand) and a Third Party (on the other hand) existing as of the "Initial Closing Date" (as such term is defined in the Share Purchase Agreement. No later than [***] ([***]) Business Days after Licensee's receipt of such notice, Licensee shall notify Ascendis whether Licensee wishes to enter into negotiations with Ascendis to negotiate an agreement for Licensee to obtain the right corresponding to such ROFN Opportunity on reasonable commercial terms to be agreed on in good faith ("ROFN License Agreement"). If Licensee does not timely notify Ascendis that it wishes to negotiate for the ROFN Opportunity, or notifies Ascendis that it is not interested in the ROFN Opportunity, Ascendis shall be free to engage with Third Parties discussions of such ROFN Opportunity, and Licensee shall have no further rights under this Clause 2.8 with respect to such ROFN Opportunity. If Licensee timely notifies Ascendis it wishes to negotiate an agreement for such ROFN Opportunity, the Parties shall enter into good faith negotiations not to exceed [***] ([***]) days with the goal of finalizing the terms of and executing such ROFN License Agreement. If after the expiration of such [***] ([***])-day period (the "ROFN Negotiation Stop Date"), the Parties have not executed such ROFN License Agreement, Ascendis shall be free to engage with Third Parties discussions of such ROFN Opportunity [***], and Licensee shall have no further rights under this Clause 2.8 with respect to such ROFN Opportunity. Notwithstanding any other provision of this Clause 2.8, in no event shall this Clause 2.8 limit in any way the ability of Ascendis or its Affiliates to engage in discussions with a Third Party for [***] to such Third Party under the Ascendis Platform Technology to [***] commercialise an Endocrinology Product so long as such discussions are not in conflict with Ascendis's obligations under Clause 2.3(A), and any such discussions shall not be deemed a "ROFN Opportunity" for which this Clause 2.8 applies.

2.9 In the event that Ascendis discontinues the development or commercialization of Licensed Product outside the Territory, or if Licensee discontinues the development or commercialization of Licensed Product in the Territory for safety, efficacy and/or regulatory reasons relating to Licensed Product (a "Qualifying Discontinuance"), Ascendis or Licensee, as the case may be, shall promptly inform the other Party of such Qualifying Discontinuance and shall provide relevant data and documentation which forms the basis of such decision to the other Party. In the event of a Qualifying Discontinuance, upon the Licensee's request, Ascendis shall provide to the Licensee [***] for its other Endocrinology Products which are [***] and for which Ascendis has not granted any Third Party [***] in the Territory, and the Licensee may elect to (i) continue activities with respect to the relevant Licensed Product in the Territory, or (ii) substitute the relevant Licensed Product with one of such other Endocrinology Products, [***], in which event such Endocrinology Product will become a Licensed Product and the Parties shall execute an amendment to this Agreement to memorialize the same. Further, if Licensee requires any technology transfer in connection with such substitution under clause (ii) of the preceding sentence, the Parties [***] the scope and timing for such transfer, as well as FTE-based payments to be made to Ascendis with respect to such transfer activities.

3. **Technical Information and Patents**

3.1 Within [***] ([***]) days of the Effective Date, Ascendis shall deliver and provide to the Licensee the items of Ascendis Technical Information listed in Schedule 2.

3.2 Ascendis shall use its Diligent Efforts to provide the Licensee with any additional Technical Information that is not specified in Schedule 2 but is Controlled by Ascendis and/or its Affiliates relating to the Ascendis Technical Information or Ascendis Platform Technology during the term of this Agreement that is necessary or useful for the Licensee to make, have made, use, sell, offer for sale or import Licensed Product in the Field in the Territory. [***].

3.3 Upon the Licensee's written request, but in no event more than [***] during the term of this Agreement, Ascendis shall provide, [***] to the Licensee a written update (as of the date the request is received by Ascendis) of the Licensed Product Patents in Schedule 1 and/or Ascendis Technical Information in Schedule 2.

4. **Development and Commercialisation**

4.1 Within [***] days following the Effective Date, the Parties shall agree to a research and technical development plan (the "Research and Technical Development Plan") that sets forth the Parties' respective Research and Technical Development Plan Activities, which may be amended from time to time by the JDC in accordance with this Agreement. The Parties shall perform and complete, or cause the performance and completion of, their respective Research and Technical Development Plan Activities, and deliver to each other a summary of the results (including raw data if reasonably requested by a Party), samples and reports arising therefrom in accordance with each Research and Technical Development Plan within [***] ([***]) days following completion thereof.

4.2 The Licensee shall provide Ascendis with a draft of each Research and Technical Development Plan. The Licensee shall consider, in good faith, any comments regarding each draft Research and Technical Development Plan that Ascendis provides to the Licensee within [***] ([***]) days of Ascendis' receipt of such draft Research and Technical Development Plan. In addition, the Licensee shall keep Ascendis informed of the progress of the development of each Licensed Product against the applicable Research and Technical Development Plan at each meeting of the JDC pursuant to Clause 4.6(A).

4.3 The Licensee shall be solely responsible for any clinical trial activities carried out as part of its development and commercialisation activities in the Territory.

4.4 The Licensee shall use Diligent Efforts to develop and commercialise Licensed Product in the Field in the Territory.

4.5 Each Party shall conduct all development of Licensed Product in compliance with current Good Laboratory Practice, Good Clinical Practice and Good Manufacturing Practice, in each case, where applicable. Neither Party shall use any person that has been debarred, disqualified or banned from practising medicine to perform activities under this Agreement, and each Party shall immediately notify the other Party in writing if any person performing activities under this Agreement is disqualified, debarred or banned from practising medicine.

4.6 **Joint Development Committee**

(A) **Formation of JDC**

Promptly after the Effective Date, the Parties will form a Joint Development Committee comprised of three (3) representatives of Ascendis and three (3) representatives of the Licensee for the first Research and Technical Development Plan (and will promptly form a JDC following agreement between the Parties in relation to each additional Research and Technical Development Plan). Ascendis agrees that it shall not have the right to nominate representatives of the Licensee to the JDC notwithstanding its ownership in the Licensee.

One representative of the Licensee at the JDC will be selected to act as the chairperson of the JDC. The JDC will meet at least [***] ([***]) times per year during the term of a Research and Technical Development Plan. Such meetings may be conducted by videoconference, teleconference or in person, as agreed by the Parties. The JDC will agree upon the time and location of the meetings. The chairperson, or his or her designee, will circulate an agenda for each meeting approximately [***] before the date scheduled for the meeting, and will include all matters requested to be included on such agenda by either Party. The chairperson, or his or her designee, will take complete and accurate minutes of all discussions occurring at the JDC meetings and all matters decided upon at the meetings except that matters reflecting legal advice of counsel will not be included in such minutes. A copy of the draft minutes of each meeting will be provided to each Party by the chairperson, or his or her designee, after each meeting, and such minutes will be reviewed by the JDC members, any needed changes discussed and final minutes agreed to and provided to each Party within [***] ([***]) days after each meeting unless otherwise agreed. A reasonable number of additional representatives of a Party may attend meetings of the JDC in a non-voting capacity. Each Party is responsible for its personnel and travel costs and expenses associated with attending meetings.

(B) **JDC functions and powers**

The responsibilities of the JDC will be as follows:

(1) encouraging and facilitating communication between the Parties with respect to the development of Licensed Product(s)) and the Research and Technical Development Plan Activities;

(2) [***] the applicable Research and Technical Development Plan's objectives, goals and schedules, and reviewing and approving amendments to the applicable Research and Technical Development Plan, [***]

(3) [***], discussing and [***] the progress of the development of Licensed Product, each Party's progress with respect to the Research and Technical Development Plan Activities for which it is responsible and each Party's diligence in carrying out its responsibilities under the applicable Research and Technical Development Plan; and

(4) carrying out the other duties and responsibilities described for it in this Agreement.

(C) **JDC decision making**

(1) All decisions of the JDC will be made by unanimous vote, with each of Ascendis and Licensee having one vote and the decisions will be recorded in the JDC minutes. If after reasonable discussion and consideration of each of the Parties' views on a particular matter before the JDC, the JDC is unable to reach a decision by unanimous vote on that matter, then [***]

The JDC shall not have any authority other than that expressly set forth above and, specifically, shall have no authority: (x) to amend or interpret this Agreement; (y) to determine whether or not a Party has met its diligence or other obligations under the Agreement; or (z) to determine whether or not a breach of this Agreement has occurred.

(D) **Termination of JDC**

The JDC shall terminate in respect of a Research and Technical Development Plan upon completion by both Parties of their respective Research and Technical Development Plan Activities, unless the Parties otherwise agree.

5. **Manufacturing**

5.1 Concurrently with the execution of this Agreement, the Parties have entered into that certain clinical supply agreement (the "Clinical Supply Agreement") pursuant to which Ascendis will supply Licensed Product to Licensee for Licensee's conduct of clinical trials for the Licensed Product in the Territory on the terms and conditions set forth in the Clinical Supply Agreement. The Parties shall discuss and negotiate in good faith the terms and conditions for the supply by Ascendis of Licensed Product to the Licensee for commercial use upon the written request of Licensee, and in any event starting no later than the date that is [***] ([***]) days after the initiation of the first pivotal clinical trial for the Licensed Product conducted by or behalf of Licensee in the Field and in the Territory.

5.2 The Licensee shall, and it shall procure that its Affiliates and any Sub-Licensees shall:

(A) [***] relating to the sale of Licensed Product comply with Applicable Laws and are marked, where required, with all relevant patent numbers; and

(B) conduct all packaging and distribution in accordance with current Good Manufacturing Practice and Good Distribution Practice.

6. **Regulatory**

6.1 The Licensee shall have the sole responsibility for obtaining and maintaining, and shall own, all Regulatory Approvals for Licensed Product developed under this Agreement from Regulatory Authorities in each of the jurisdictions in the Territory in the Field.

6.2 Ascendis hereby grants to the Licensee, its Affiliates and Sub-licensees the right to access, reference and utilize any data (including clinical trial data) or regulatory filings generated and/or filed by or on behalf of Ascendis or its Affiliates or other licensees (in each case, to the extent Controlled by Ascendis or its Affiliates) with respect to Licensed Product(s)) in connection with the development, Manufacturing and commercialisation by the Licensee, its Affiliates and Sub-licensees of Licensed Product(s) in the Territory, free of additional charge, as set forth herein. Upon written request from Licensee to be provided access to any such information, Ascendis shall provide such access to Licensee within a reasonable time frame, taking into account the development and regulatory activities conducted by or on behalf of Ascendis for the Licensed Products outside of the Territory. Ascendis hereby represents and warrants that, as of the Effective Date, it and/or its Affiliates Control all data and regulatory filings generated and/or filed by or on behalf of Ascendis or its Affiliates or other licensees with respect to the Licensed Product and Ascendis has the right to grant the right to access, reference and utilization to Licensee, its Affiliates and Sub-licensees thereto. During the Term, Ascendis and/or its Affiliates shall maintain the right to all data and regulatory filings generated and/or filed by or on behalf of Ascendis or its Affiliates or other licensees with respect to the Licensed Product (including by reserving the rights from any Third Party generating, filing and/or having rights to any and all such data and/or regulatory filings) so that Ascendis and/or its Affiliates retains Control of such data and regulatory filings and can grant the right to access, reference and utilization to Licensee, its Affiliates and Sub-licensees under this Section 6.2.

6.3 The Licensee hereby grants to Ascendis the right to access, reference and utilize any data (including clinical trial data) or regulatory filings generated and/or filed by or on behalf of the Licensee or its Affiliates or sublicensees (in each case, to the extent Controlled by Licensee or its Affiliates) with respect to Licensed Product(s) in connection with the development, Manufacturing and commercialisation by Ascendis, its Affiliates or other licensees of Licensed Product(s) outside the Territory, free of additional charge, as set forth herein. Upon written request from Ascendis to be provided access to any such information, Licensee shall provide such access to Ascendis within a reasonable time frame, taking into account the development and regulatory activities conducted by or on behalf of Licensee for the Licensed Products in the Field in the Territory. During the Term, Licensee and/or its Affiliates shall maintain the right to all data and regulatory filings generated and/or filed by or on behalf of Licensee or its Affiliates or Sub-licensees with respect to the Licensed Product (including by reserving the rights from any Third Party generating, filing and/or having rights to any and all such data and/or regulatory filings) so that Licensee and/or its Affiliates retains Control of such data and regulatory filings and can grant the right to access, reference and utilization to Ascendis, its Affiliates and other licensees under this Section 6.2.

6.4 The Licensee undertakes to comply, and to procure that its Sub-Licensees and contractors comply, with all requirements of Regulatory Authorities and/or Applicable Law and relevant guidance.

6.5 Ascendis shall provide assistance and information as reasonably requested by the Licensee in support of such regulatory activities[***].

7. **Payments**

7.1 **Upfront**

As a one-time, non-refundable consideration of the rights and licence granted by Ascendis to Licensee under this Agreement, Licensee shall issue and transfer to Ascendis [***] Series A-1 Preferred Shares in VISEN Pharmaceuticals, corresponding to a total value of US[***] at the Effective Date.

7.2 **Research and development funding**

The Licensee shall pay or reimburse (as applicable) Ascendis for the Research and Technical Development Plan Expenses in accordance with the schedule set forth in the Research and Technical Development Plans.

7.3 **Taxes**

In the event that the Licensee is required, under applicable laws, to withhold any deduction or tax from any payment due to Ascendis under this Agreement, such amount shall be deducted from the payment to be made by the Licensee, paid to the proper taxing authority, provided that the Licensee shall take reasonable and lawful actions to avoid and minimise such withholding and promptly notify Ascendis so that Ascendis may take lawful actions to avoid and minimise such withholding. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time-to-time in effect.

All sums payable by the Licensee under or pursuant to this Agreement [***] (if applicable). The taxable supply of services made under or in connection with this Agreement by Ascendis to the Licensee are [***]. The Parties agree that they will undertake commercially reasonable efforts to minimize or eliminate any VAT liability, including but not limited to [***].

7.4 **Interest**

Where any fees, milestones or other sums payable by the Licensee to Ascendis hereunder remain unpaid after the date on which they became due, the Licensee shall pay to Ascendis interest calculated from the date upon which the sums became due until payment thereof at the rate, to the extent permitted by applicable law, equal to the average one-month US Dollar London Interbank Offered Rate (LIBOR) as determined for each Quarterly Period on the last Business Day of such Quarterly Period (it being understood that if such rate is below zero percent (0%) for any period it shall be deemed to be zero percent (0%) for such period for the purposes of this Clause 7.4) plus [***] percent ([***]%).

8. **Records and Auditing**

8.1 Each Party will maintain complete and accurate books, records and accounts used for the determination of any payment obligations under this Agreement, which books, records and accounts will be retained by such Party until [***] ([***]) years after the end of the period to which such books, records and accounts pertain. The Licensee shall make such books, records and accounts available to Ascendis for an additional [***] ([***]) years if reasonably available and required by the applicable tax authority.

9. **Pharmacovigilance**

9.1 After the execution of this Agreement, the Parties shall promptly, and in any event before the Licensee starts any clinical development activities, agree on the terms of a safety data exchange agreement (the "SDEA") for the collection, reporting and exchange of safety information. The scope of the SDEA shall also include the Licensee's Affiliates and Sub-Licensees, as applicable.

9.2 Each Party shall notify the other Party of any "serious adverse experience" or "unexpected adverse experience" (as defined below) and will manage the same, both in accordance with the terms of the SDEA. For the purpose of this Clause 9.2, "serious adverse experience" and "unexpected adverse experience" shall have the meaning assigned by relevant regulations (to the extent applicable). To the extent relevant regulations require harmonisation or are not applicable, then each of the foregoing terms shall be as defined in the SDEA.

10. **Confidentiality**

10.1 During the term of this Agreement, and for a period of [***] ([***]) years thereafter, the Licensee agrees to keep secret Ascendis' Confidential Information, to use the same exclusively as permitted under this Agreement, and to disclose the same only to those of its employees, contractors, consultants, Affiliates and Sub-Licensees to whom and to the extent that such disclosure is reasonably necessary in order to exercise its rights and perform its obligations under this Agreement.

10.2 During the term of this Agreement, and for a period of [***] ([***]) years thereafter, Ascendis agrees to keep secret the Licensee's Confidential Information, to use the same exclusively as permitted under this Agreement, and to disclose the same only to those of its employees, contractors, Affiliates, Sub-Licensees and licensees to whom and to the extent that such disclosure is reasonably necessary in order to exercise its rights and perform its obligations under this Agreement.

10.3 Each Party shall procure that all its employees, contractors, Affiliates and Sub-Licensees who have access to any Confidential Information of the other to which the obligations of Clauses 10.1 or 10.2 as the case may be apply, shall be made aware of, subject to, and comply with those obligations. Without limiting the foregoing, each Party shall take at least those measures it employs to protect its own confidential information of a similar nature to protect the other Party's Confidential Information, but in any event no less than reasonable care.

10.4 The foregoing obligations of Clauses 10.1 and 10.2 shall not apply to any Confidential Information of the disclosing Party which:

(A) prior to the recipient Party's receipt thereof from the disclosing Party, was in the possession of the recipient Party without any breach of confidentiality and at its free disposal;

(B) is subsequently lawfully disclosed to the recipient Party without any breach of confidentiality by an independent Third Party, and at the recipient Party's free disposal;

(C) is or becomes generally available to the public through no act or default of the recipient Party or its agents, contractors or employees; or

(D) is independently developed by the receiving Party without the benefit of any Confidential Information disclosed hereunder, as demonstrated by documented evidence prepared contemporaneously with such independent development.

10.5 Notwithstanding the foregoing, a Party and its Affiliates and Sub-Licensees may use and disclose the Confidential Information of the other Party:

(A) if it is required to be disclosed by law, regulation or action of any governmental agency or authority, including as may be required in connection with any filings made with, or by the disclosure policies of a major stock exchange; provided that the Party seeking to disclose the Confidential Information of the other Party: (i) promptly informs the other Party (prior to making any such disclosures, if practicable) and cooperates with the other Party in seeking a protective order or other appropriate remedy (including redaction); and (ii) whenever it is possible to obtain confidential treatment, request confidential treatment of such information;

(B) as reasonably necessary to obtain or maintain any Regulatory Approval, including to conduct preclinical studies and clinical trials and for pricing approvals, for any Licensed Product, provided that, the disclosing Party shall use commercially reasonable efforts to limit disclosure of the Confidential Information outside such regulatory agency and to otherwise maintain the confidentiality of the Confidential Information; or

(C) as reasonably necessary to exercise its rights or fulfil its obligations under this Agreement.

10.6 The Licensee and its Affiliates and Sub-Licensees may disclose the Confidential Information of Ascendis to contractors, consultants and other service providers in connection with the development or Manufacture of Licensed Product(s) under conditions of confidentiality at least as restrictive as those contained in this Clause 10 and/or as is standard for similar deals in the biotechnology industry.

10.7 If a Party concludes that a copy of this Agreement must be filed with the United States Securities Exchange Commission or other regulatory agency ("SEC") (or equivalent foreign agency or a securities exchange), such Party will use all reasonable efforts to provide the other Party with a copy of this Agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, and to provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions. The filing Party will take such other Party's reasonable comments into consideration before filing the Agreement.

10.8 Each Party ("Publishing Party") shall submit to the other Party manuscripts, including abstracts, and texts of poster presentations and other external presentations containing the other Party's Confidential Information at least [***] ([***]) days prior to presentation or submission for publication for purposes of allowing the other Party to comment on the manuscript or text; provided that the other Party may require the Publishing Party, by giving notice in writing to the Publishing Party within [***] ([***]) days of the receipt of such manuscript, abstract, text or other external presentations from the Publishing Party to redact certain information or delay submission for publication or presentation of such manuscript, abstract, text or other external presentation if, in the reasonable opinion of the other Party such delay is necessary in order to permit the filing of any patent application or to protect the other Party's Confidential Information contained in such manuscript, abstract, text or other external presentation.

10.9 The Licensee, in accordance with its internal policies and procedures, shall have the right to publish all studies, clinical trials and results thereof on the clinical trial registries that are maintained by or on behalf of the Licensee. Ascendis shall not publish any studies, clinical trials or results thereof on its clinical trial registry, provided however, that Ascendis may include on Ascendis' clinical trial registry a link to the Licensee's clinical trial registry.

10.10 Notwithstanding the foregoing, each Party shall have the right to disclose the terms and conditions of this Agreement: (i) in confidence (i.e., pursuant to a written confidentiality agreement containing terms at least as stringent as those contained in this Agreement) to any bona fide potential or actual investor, investment banker, auditor, counsel, acquirer or merger target; and (ii) subject to the prior written consent of the other Party, such consent not to be unreasonably withheld, for the purpose of a public offering or private placement of shares and/or securities.

11. **Intellectual Property**

11.1 All Patents and Technical Information and other Intellectual Property owned or Controlled by a Party prior to the Effective Date shall remain owned or Controlled by the respective Party.

11.2 Ascendis and the Licensee acknowledge and agree that as between them:

(A) Ascendis (or its Affiliates) shall own all right, title and interest in and to any and all Ascendis Patents (except for Ascendis Patents within the Joint Program IP), Ascendis Technical Information (except for Ascendis Technical Information within the Joint Program IP) and Ascendis Program IP;

(B) the Licensee shall own all right, title and interest in and to any and all Licensee Program IP; and

(C) the Licensee and Ascendis (or its Affiliates) shall each own an undivided fifty percent (50%) right, title and interest in and to any and all Joint Program IP. For the avoidance of doubt, subject to the licences granted under this Agreement, each Party shall be free to exploit, transfer or encumber its own interest in the Joint Program IP without the consent of, and without accounting to, the other Party. For those jurisdictions where a specific license is required for a joint owner of Joint Program IP to practice such Joint Program IP in such jurisdictions: (i) Ascendis hereby grants to Licensee a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable license under Ascendis's right, title and interest in and to all Joint Program IP to use such Joint Program IP in accordance with the terms of this Agreement; and (ii) Licensee hereby grants to Ascendis a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable license under Licensee's right, title and interest in and to all Joint Program IP to use such Joint Program IP in accordance with the terms of this Agreement. Each Party shall promptly notify the other Party after it first learns of the conception of a Joint Program IP by such Party, its employees, officers, or independent contractors, and provide the other Party with a detailed report of the underlying data, results, experimental procedures related to, and inventors of, such Joint Program IP.

11.3 Notwithstanding the foregoing, [***].

12. **Prosecution, Maintenance and Defence**

12.1 Subject to Clause 12.4, Ascendis shall, at its own expense and in its sole discretion, have the right to file, prosecute, maintain and defend the Ascendis Patents that are not Joint Program IP Patents (as defined in Clause 12.3(A) (including without limitation Licensed Product Patents as well as any Ascendis Patent claiming Ascendis Platform Technology that are not Joint Program IP Patents). Solely with respect to the Licensed Product Patents in the Territory that are not within the Joint Program IP, Ascendis will promptly provide the Licensee with drafts of all proposed filings and correspondence (including without limitation the initial application as well as any material correspondence with any Intellectual Property Office in the Territory related to any filings) in a manner that allows the Licensee a reasonable opportunity for review and comment (and in any event no less than [***] ([***]) days, if and when possible) before such filings are due. Ascendis will consider all of the Licensee's reasonable suggestions, recommendations and instructions concerning the preparation, filing, prosecution, defence and maintenance of any such Patents (including without limitation any suggestion or recommendation [***]), provided that such reasonable suggestions, recommendations and instructions are provided to Ascendis within [***] ([***]) days of the Licensee receiving any such proposed filings and correspondence. If Ascendis does not wish to file, prosecute or maintain any such Licensed Product Patent which is not within the Joint Program IP, or if Ascendis wishes to allow any such Patent to lapse, in each case, solely within the Territory, then [***], Ascendis shall notify Licensee in writing of such decision at least [***] ([***]) days prior to any action relating to such Patent is required, and Licensee shall then have the option, at its sole discretion, to file, prosecute, and/or maintain such Patent, at its sole cost and expense.

12.2 Subject to Section 12.4, the Licensee shall, at its own expense and in its sole discretion, have the right to file, prosecute, maintain and defend any Patent within the Licensee Program IP. If Licensee does not wish to file, prosecute or maintain any such Patent within the Licensee Program IP, or if Licensee wishes to allow any such Patent to lapse, in each case, solely outside of the Territory, then [***], Licensee shall notify Ascendis in writing of such decision at least [***] ([***]) days prior to any action relating to such Patent is required, and Ascendis shall then have the option, at its sole discretion, to file, prosecute, and/or maintain such Patent, at its sole cost and expense.

12.3 **Joint Program IP**

(A) Subject to Clause 12.4, the Prosecuting Party (as defined below) shall select outside patent counsel ("Outside Patent Counsel") at its sole discretion to file, prosecute and maintain any Patent within the Joint Program IP in the joint names of the Parties ("Joint Program IP Patent"). [***] shall have the first right, at its sole expense and in its sole discretion, to engage Outside Patent Counsel to file, prosecute and maintain all Joint Program IP Patents, and [***] shall have the backup right to file, prosecute, and maintain such Joint Program IP Patents in the Territory in accordance with Clause 12.3(C). The Party that exercises its right to file, prosecute and maintain a particular Joint Program IP Patent in accordance with this Clause 12.3 shall be referred to as the "Prosecuting Party".

(B) With respect to Joint Program IP Patents, the Prosecuting Party will (or will cause Outside Patent Counsel to) promptly provide the other Party with drafts of all proposed filings and correspondence (including without limitation the initial application as well as any material correspondence with any Intellectual Property Office related to any filings) in a manner that allows the other Party a reasonable opportunity for review and comment (and in any event no less than [***] ([***]) days, if and when possible, before such filings are due). The Prosecuting Party will (or will cause Outside Patent Counsel to) consider all of the other Party's reasonable suggestions, recommendations and instructions concerning the preparation, filing, prosecution, defence and maintenance of any such Joint Program IP Patents (including without limitation any suggestion or recommendation [***]), provided that such reasonable suggestions, recommendations and instructions are provided to the Prosecuting Party (or Outside Patent Counsel) within [***] ([***]) days of the other Party receiving any such proposed filings and correspondence.

(C) If [***] as the Prosecuting Party elects: (1) not to file, prosecute or maintain a Joint Program IP Patent (whether in one or more jurisdictions); or (2) to allow any such Patent to lapse or become abandoned or unenforceable, in each case, in accordance with Clause 12.3(A), then [***] shall notify [***] in writing at least [***] ([***]) days prior to the lapse or abandonment of any such Patent. Thereafter, [***] may, but is not required to, undertake, at its sole expense and in its sole discretion, and using Outside Patent Counsel, the prosecution and maintenance of such Joint Program IP Patent, but solely within the Territory, and in such case, [***] shall become the Prosecuting Party with respect to such Patent in the Territory.

12.4 Notwithstanding any other provision of this Clause 12, [***]

12.5 The Parties agree to cooperate reasonably in the filing, prosecution and maintenance of all Patents as set forth under this Clause 12 including providing relevant Technical Information to the prosecuting Party (as determined in accordance with this Clause 12), obtaining and executing necessary powers of attorney and assignments by the named inventors, obtaining execution of such other documents which may be needed in the filing, prosecution and maintenance of each such Patent, and, as requested, updating each other regarding the status of each such Patent, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession and Control that is reasonably necessary to prosecute and maintain such Patents.

13. **Enforcement of Patent Rights and Defence of Third Party Claims**

13.1 **Infringement by a Third Party**

(A) In the event of Ascendis or the Licensee becoming aware of any suspected infringement or any unauthorised use by a Third Party of any of the Ascendis Patents, Ascendis Technical Information, Ascendis Program IP, Licensee Program IP, and/or the Joint Program IP in the Field in the Territory, the Party becoming aware of the same shall promptly notify the other Party.

(B) Where such suspected infringement or unauthorised use is of the Ascendis Patents or Ascendis Technical Information (including those within the Joint Program IP and/or Ascendis Program IP), in each case (i) outside the Territory, or (ii) inside the Territory but outside the Field, Ascendis shall, at its own expense, have the exclusive right, but not the obligation, to take or threaten any legal action that it deems appropriate to halt such suspected infringement and to retain any amounts recovered in respect of such suspected infringement or unauthorised use. Termination and/or settlement of the litigation are at the sole discretion of Ascendis (i.e., without the prior consent of the Licensee), provided such termination or settlement does not impose a liability (monetary or otherwise) on Licensee or limit the rights of Licensee under this Agreement, or otherwise materially impair Licensee's rights in the relevant Ascendis Patent in each case without Licensee's prior written consent.

(C) Where such suspected infringement or unauthorised use is of the Ascendis Patents Ascendis Technical Information (including those within the Joint Program IP and/or any Ascendis Program IP), in each case in the Field in the Territory, the Licensee shall, at its own expense, have the first right, but not the obligation to take or threaten any legal action that it deems appropriate to halt such suspected infringement (provided that [***]). Each Party shall retain the following percent of any remaining amounts recovered in respect of such suspected infringement or unauthorised use after the Licensee has recouped its expenses: the Licensee shall retain [***] percent ([***]%) and Ascendis shall retain [***] percent ([***]%). Termination and/or settlement of the litigation are at the sole discretion of the Licensee (i.e., without the prior consent of Ascendis), provided such termination or settlement does not impose a liability (monetary or otherwise) on Ascendis or limit the rights of Ascendis under this Agreement, or otherwise materially impair Ascendis's rights in the relevant Ascendis Patent in each case without Ascendis's prior written consent.

(D) If Ascendis wishes to take or threaten legal action and the Licensee has the first right to do so under Clause 13.1(C), but does not do so within [***] ([***]) days of becoming aware of potential infringement, then Ascendis may take or threaten such legal action and the Licensee shall, at Ascendis' request, lend its name where necessary or desirable to proceedings relating to such action and provide reasonable assistance in such proceedings. In such circumstances, Ascendis shall control the conduct of the action but shall consult the Licensee in good faith with regard to significant decisions. Each Party shall retain the following percent of any remaining amounts recovered in respect of such suspected infringement or unauthorised use after Ascendis has recouped its expenses: Ascendis shall retain an amount equal to [***] percent ([***]%) and the Licensee shall retain the remaining [***] percent ([***]%). Termination and/or settlement of the litigation are at the sole discretion of Ascendis (i.e., without the prior consent of the Licensee).

(E) Each Party shall provide to the Party enforcing any such rights under this Clause 13.1 reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by Applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any important aspects of such enforcement, including determination of litigation strategy and filing of important papers to the competent court.

13.2 **Defence of Third Party Claims**

(A) In the event that the development or commercialisation of a Licensed Product results in action by a Third Party against a Party (or its Affiliates or Sub-Licensees) for infringement or unauthorised use of Intellectual Property or confidential information anywhere in the Territory, such Party shall promptly notify the other Party in writing.

(B) Each Party (or its Affiliates or Sub-Licensees) against whom such action is brought shall: (i) have the right but not the obligation to defend such action; (ii) have the right to be represented by separate legal advisors; (iii) keep the other Party informed of, and assist and co-operate with the other Party in, any such action; and (iv) bear its own costs.

14. **Warranties**

14.1 Each Party warrants to the other Party that it:

(A) is free to enter into this Agreement and to carry out its obligations hereunder without violating any obligation owed by it or any of its Affiliates to any Third Party;

(B) shall not, during the existence of this Agreement, enter into any assignments, licences, obligations, charges or assignments, either written, oral or implied, which are or shall be inconsistent with this Agreement;

(C) has obtained all necessary corporate approvals to enter into and execute this Agreement;

(D) has never been debarred, disqualified or banned from practising medicine and that it is not under investigation by any Regulatory Authority for debarment, disqualification or any similar regulatory action in any country.

14.2 Ascendis represents and warrants to the Licensee that, as of the Effective Date, Ascendis:

(A) Controls the Ascendis Patents and Ascendis Technical Information in the Field in the Territory;

(B) has the right to grant to the Licensee the rights and licences granted to the Licensee under the terms and conditions of this Agreement,

(C) has the right to provide and disclose to the Licensee the Ascendis Technical Information that it provides or discloses to the Licensee under the terms and conditions of this Agreement;

(D) itself and its employees have not received notice of any actions, lawsuits, claims or arbitration or material adverse proceedings (other than on-going routine patent prosecution matters) in any way relating to the Ascendis Patents, Ascendis Technical Information or Ascendis Platform Technology; and

(E) is not, to [***] its knowledge, aware that the use of Licensed Product Patents in Schedule 1, the Ascendis Patents existing as of the Effective Date, and/or Ascendis Technical Information listed in Schedule 2, for development or commercialisation of a Licensed Product infringes any Third Party's Patent.

(F) there are no patents, patent applications or Technical Information that are owned or in-licensed by Ascendis and/or its Affiliates that Ascendis and/or its Affiliates do not Control and are not included in the license granted to Licensee under this Agreement, which would be infringed by or would otherwise cover the development, manufacture and/or commercialization of the Licensed Product in the Field in the Territory. During the Term, Ascendis and/or its Affiliates shall maintain the Control of patents, patent applications and/or Technical Information that are then-owned or then-in-licensed by Ascendis and/or its Affiliates that would be infringed by or would otherwise cover the development, manufacture and/or commercialization of the Licensed Product in the Field in the Territory (including by reserving such rights from any Third Party carrying out the development, manufacture and/or commercialization of the Licensed Product on behalf of or under a license from Ascendis or its Affiliates) so that such patents, patent applications and/or Technical Information are included in the license granted to Licensee hereunder; provided, that for clarity this provision shall not be deemed to impose any obligation on Ascendis to obtain ownership or license rights to any patents, patent applications, Technical Information, or intellectual property rights of any Third Party.

14.3 EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO INTELLECTUAL PROPERTY RIGHTS OR CONFIDENTIAL INFORMATION SUPPLIED BY IT TO THE OTHER PARTY HEREUNDER, AND EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT.

15. **Indemnification**

15.1 Except as provided in Clause 15.2 below, the Licensee shall indemnify, defend and hold harmless Ascendis and its Affiliates, and their respective directors, officers, employees and agents (each an "Ascendis Indemnitee") from and against all Losses arising out of or resulting from any Third Party Claims to the extent such Losses result from or arise out of: (a) the activities performed by the Licensee in connection with the exercise of its rights or obligations under this Agreement (including the exploitation of the Licensed Product(s) in the Territory); (b) breach by the Licensee of the representations and warranties provided in Clause 14; (c) gross negligence, recklessness or wilful misconduct by the Licensee; or (d) violation of Applicable Law by the Licensee. The indemnification obligations set forth in this Clause 15.1 shall not apply to the extent that any such Losses arising from such Third Party Claim arose or resulted from the events specified in Clause 15.2(a)-(d).

15.2 Except as provided in Clause 15.1 above, Ascendis shall indemnify, defend and hold harmless the Licensee, its Affiliates, and their respective directors, officers, employees and agents (each a "Licensee Indemnitee") from and against all Losses arising out of or resulting from any Third Party Claims to the extent such Losses result from or arise out of: (a) the activities performed by Ascendis, its Affiliates, and Sublicensees in connection with the exercise of its rights or obligations under this Agreement, including the exploitation of the Licensed Product(s) outside of the Territory; (b) breach by Ascendis of the representations and warranties provided in Clause 14; (c) gross negligence, recklessness or wilful misconduct by Ascendis, its Affiliates, and Sublicensees; or (d) violation of Applicable Law by Ascendis, its Affiliates, and Sublicensees. The indemnification obligations set forth in this Clause 15.2 shall not apply to the extent that any such Third Party Claim arose or resulted from the events specified in Clause 15.1(a)-(d).

15.3 In the event that an Ascendis Indemnitee or a Licensee Indemnitee, as applicable (hereinafter an "Indemnified Party") seeks indemnification under this Clause 15, such Indemnified Party shall: (i) give prompt notice to the indemnifying Party of any such Third Party Claim; (ii) permit the indemnifying Party to assume direction and control of the defence of such Third Party Claim (including decisions regarding its settlement or other disposition, which may be made in the indemnifying Party's sole discretion except as otherwise provided herein); (iii) assist the indemnifying Party at the indemnifying Party's expense in defending such Third Party Claim; and (iv) not compromise or settle such Third Party Claim without the indemnifying Party's prior written consent, which shall not be unreasonably withheld or delayed. The failure to deliver written notice to the indemnifying Party within a reasonable time after the commencement of any such Third Party Claim, to the extent prejudicial to its ability to defend such Third Party Claim, shall relieve the indemnifying Party of any obligation to the Indemnified Party under this Clause 15. The Indemnified Party may participate in the defence of such Third Party Claim through counsel of its choice, but the reasonable cost of such counsel shall be borne solely by the Indemnified Party. It is understood that only Ascendis or the Licensee may claim indemnity under this Clause 15 (on its own behalf or on behalf of its Indemnified Parties), and other Indemnified Parties may not directly claim indemnity hereunder. No compromise or settlement of any Third Party Claim may be effected by the indemnifying Party without the Indemnified Party's prior written consent (which consent shall not be unreasonably withheld or delayed), unless: (a) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnified Party; (b) the sole relief provided is monetary damages that are paid in full by the indemnifying Party; and (c) the Indemnified Party's rights under this Agreement are not adversely affected. The Indemnified Party shall have no right to settle any such Third Party Claim without the prior written consent of the indemnifying Party (and any such settlement without the prior written consent of the indemnifying Party shall relieve the indemnifying Party of its obligations under this Clause 15), unless: (x) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnifying Party; (y) the sole relief provided is monetary damages that are paid in full by the Indemnified Party; and (z) the indemnifying Party's rights under this Agreement are not adversely affected.

16. **Limitation of Liability**

16.1 Subject to Clause 16.2, neither of the Parties nor any of their Affiliates shall be liable to each other under any contract, negligence, strict liability or other legal or equitable theory for indirect, incidental, special, punitive, exemplary or consequential damages arising out of or resulting from this Agreement. The foregoing shall not limit:

(A) the obligations of either Party from and against Third Party claims under Clauses 15.1 or 15.2 to the extent that such Third Party has been awarded such damages;

(B) the liability of a Party as a result of its breach of Clause 10; or

(C) the liability of either Party under Clause 2.3.

16.2 Neither Party limits or excludes its liability for fraud, fraudulent concealment or fraudulent misrepresentation, nor for death or personal injury arising from its negligence.

16.3 Ascendis and Ascendis Pharma A/S shall be jointly and severally liable for any liabilities incurred by or on behalf of Ascendis under this Agreement.

17. **Term and Survival**

17.1 This Agreement shall commence with effect from the Effective Date and shall continue for so long as a Valid Claim of an Ascendis Patent exists in the Territory, unless terminated earlier pursuant to Clause 18.

17.2 On the expiration or other termination of this Agreement each Party shall continue to be bound by Clauses 2.2 (solely in the event of expiration, or as it may be modified by Clause 19.3 in specified events of termination), 8 (Records and Auditing), 9.2 (Pharmacovigilance), 10 (Confidentiality), 11.1and 11.2 (Intellectual Property), 15 (Indemnification), 16 (Limitation of Liability), 17 (Term and Survival), 19 (Effect of Termination), 20 (Dispute Resolution) and 21 (Miscellaneous).

18. **Termination**

18.1 **Licensee termination for convenience**

The Licensee may terminate this Agreement at any time for any reason by giving ninety (90) days' prior written notice to Ascendis.

18.2 **Right to Terminate for Material Breach**

(a) In the event that Ascendis commits a material breach of any of the terms of this Agreement on its part to be performed or observed, Licensee shall have the right to terminate this Agreement, in whole or in part, by giving sixty (60) days' written notice to Ascendis; provided, however, that in the case of a material breach capable of being remedied, if Ascendis shall remedy such material breach within sixty (60) days after the notice has been given, then the notice shall not be effective and the Agreement shall not terminate.

(b) In the event that Licensee commits a material breach of any of the material obligations under Section 2.3, 7.1, 7.2 or 10 and such material breach causes material loss by Ascendis that exceeds [***] dollars ($[***]), Ascendis shall have the right to terminate this Agreement, in whole or in part, by giving ninety (90) days' written notice to Licensee; provided, however, that if Licensee shall remedy such material breach or reduce such loss below [***] dollars ($[***]) within ninety (90) days after the notice has been given, then the notice shall not be effective and the Agreement shall not terminate.

18.3 **Right to Terminate for Bankruptcy**

(A) **Right to terminate**

A Party (the "Non-Bankrupt Party") may, to the extent legally permissible and in addition to any other remedies available to it by law or in equity, terminate this Agreement, as a whole by notice to the other Party (the "Bankrupt Party"), in the event the Bankrupt Party has become bankrupt, has made an assignment for the benefit of its creditors or there has been appointed a trustee or receiver of the Bankrupt Party for all or a substantial part of its property or any case or proceeding shall have been commenced or other action taken by or against the Bankrupt Party in bankruptcy or seeking reorganisation, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganisation or other similar act or law of any jurisdiction now or hereafter in effect and any such event shall have continued for sixty (60) days undismissed, unbonded and undischarged.

(B) **Retention of rights upon Bankruptcy**

In the event of a bankruptcy of the Bankrupt Party, the rights and licences granted under or pursuant to this Agreement by the Bankrupt Party to the Non-Bankrupt Party are, and shall otherwise be deemed to be, for purposes of paragraph 365(n) of the United States Bankruptcy Code, licences of rights to "intellectual property" as defined under paragraph 101(35A) of the United States Bankruptcy Code. The Parties agree that the Non-Bankrupt Party, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code. The Parties further agree that in the event of the commencement of a bankruptcy proceeding by or against the Bankrupt Party, including under the United States Bankruptcy Code, the Non-Bankrupt Party shall, to the extent legally permissible, be entitled to complete access to any such intellectual property of the Bankrupt Party that pertains to the rights granted in the licenses under this Agreement and embodiments of such intellectual property.

18.4 **Ascendis termination for Change of Control.** Ascendis may terminate this Agreement as a whole, [***] written notice to Licensee, in the event of a Change of Control in favour of a Competitor.

18.5 **Ascendis termination for Patent challenge.**

(A) Without limiting Clause 18.5(B), [***], Ascendis may terminate this Agreement as a whole effective upon thirty (30)-day written notice to the Licensee, if the Licensee or its Affiliates challenges [***] in a court the validity, [***] of any Ascendis Patent and such challenge is not withdrawn within such thirty (30)-day period, unless Ascendis or its Affiliates or any of its licensees has [***].

(B) At any time during the Term, Ascendis may terminate this Agreement as a whole effective upon thirty (30)-day written notice to the Licensee, if the Licensee or its Affiliates challenges [***] in a court the validity, [***] of any (i) Ascendis Patent [***] or (ii) any Ascendis Patent [***], and in either case of (i) or (ii), such challenge is not withdrawn within such thirty (30)-day period, unless Ascendis or its Affiliates or any of its licensees has [***].

19. **Effect of Termination**

19.1 The termination of this Agreement shall be without prejudice to:

(A) the obligation of the Licensee to pay to Ascendis all sums accrued, due and payable under Clause 7 as of the effective date of termination; and

(B) any right of, or remedy available to, either Party against the other in respect of any action or omission hereunder prior to such termination.

19.2 **Termination by the Licensee**

(A) **For Convenience**

In the event of termination of this Agreement in whole or in part by the Licensee pursuant to Clause 18.1:

(1) the licences granted to Ascendis and its Affiliates under Clause 2.2 shall [***], except that [***], and [***];

(2) Licensee shall transfer, or cause to be transferred, all [***] existing as of the effective date of such termination to Ascendis or its designee, [***], and Ascendis shall [***];

(3) the licences granted to the Licensee under Clause 2.1 shall terminate as of the effective date of such termination;

(4) [***]; and

(5) obligations under Clause 2.3 shall cease for both Parties and their Affiliates.

(B) **For Ascendis' breach or bankruptcy**

In the event of termination of this Agreement in whole by the Licensee pursuant to Clauses 0 or 18.3(A), subject to Clause 19.5:

(1) the licence granted to the Licensee under Clause 2.1 (and all sublicenses granted thereunder) shall survive (along with all obligations associated therewith) in respect of any Ascendis Patents, Ascendis Technical Information, Ascendis Program IP and Ascendis' and its Affiliates' interest in Joint Program IP that exist as of the effective date of such termination;

(2) the licence granted to Ascendis and its Affiliates under Clause 2.2 shall survive (along with all obligations associated therewith), in respect of the Licensee's and its Affiliates' interest in any Joint Program IP and Licensee Program IP that exist as of the effective date of such termination;

(3) [***];

(4) if the effective date of such termination is prior to the [***] anniversary of the Effective Date, unless otherwise agreed to by the Licensee, Ascendis' obligations under Clause 5.1 shall survive until the [***] anniversary of the Effective Date; and

(5) Ascendis' and its Affiliates' obligations under Clause 2.3(A) shall survive until the [***] anniversary of the effective date of such termination.

19.3 **Termination by Ascendis**

In the event of termination of this Agreement in whole or in part by Ascendis pursuant to Clauses 18.2, 18.3, 18.4 or 18.5, subject to Clause 19.4:

(A) the licence granted to Ascendis and its Affiliates under Clause 2.2 shall [***], except that [***], and Ascendis [***];

(B) Licensee shall transfer, or cause to be transferred, [***] existing as of the effective date of such termination to Ascendis or its designee, [***], and Ascendis shall [***];

(C) [***];

(D) obligations under Clause 2.3 shall cease for both Parties and their Affiliates; and

(E) the licence granted to the Licensee under Clause 2.1 shall terminate as of the effective date of the termination.

19.4 **Inventory at termination**

In the event this Agreement is terminated for any reason, the Licensee shall have the right to sell or otherwise dispose of Licensed Product then in its stock for up to [***] ([***]) months following the termination of this Agreement.

19.5 **Continuation of sub-licences**

Upon termination of this Agreement, any existing, permitted sub-licence granted by a Party under this Agreement shall continue in full force and effect, provided that the permitted Sub-Licensee did not cause the breach that gave rise to a termination under Clause 18.2 and agrees to be bound by all the terms and conditions of this Agreement that are applicable to such permitted Sub-Licensee, including, without limitation, rendering directly to the licensing Party all payments and other obligations due to the licensing Party related to such sub-licence.

19.6 **Return of Confidential Information**

Following any expiration or termination of this Agreement, the Party that has Confidential Information of the other Party shall return to the other Party (or destroy at such Party's written request) all such Confidential Information in its possession as of the effective date of expiration or termination (with the exception of one copy of such Confidential Information, which may be retained by the legal department of the Party that received such Confidential Information to confirm compliance with the non-use and non-disclosure provisions of this Agreement, and any Confidential Information of the other Party contained in its laboratory notebooks or databases.

20. **Dispute Resolution**

20.1 **Internal resolution**

(A) Any dispute, controversy or claim related to matters within the powers and authority of the JDC shall be resolved by the Parties in accordance with procedures set forth in Clause 4.6.

(B) Except as otherwise expressly provided herein, including in Clause 20.1(A) above, in the event of any controversy, claim or other dispute arising out of or relating to compliance with this Agreement, or the validity, breach, termination or interpretation of this Agreement, such dispute shall be first referred to the Executives for resolution, prior to proceeding under the following provisions of Clause 20.2. A dispute shall be referred to the Executives upon one Party providing the other Party with written notice that such dispute exists, and the Executives shall attempt to resolve such dispute through good faith discussions. In the event that the Executives cannot resolve such dispute within [***] ([***]) days of such other Party's receipt of such written notice, either Party may initiate the dispute resolution procedures set forth in Clause 20.2. The Parties agree that any discussions between such Executives, or their designees, regarding such dispute shall be the Confidential Information of both Parties and do not constitute settlement discussions, unless the Parties agree otherwise in writing.

20.2 **Arbitration**

Except as otherwise expressly provided in this Agreement, including but not limited to Clause 20.3, the Parties agree that any dispute not resolved internally by the Parties pursuant to Clause 20.1(B), shall be resolved through binding arbitration conducted under the auspices of the [***] (for purposes of this Clause 20.2, the "Rules"), except as modified in this Agreement, applying the substantive law specified in Clause 21.12 (Governing law). A Party may initiate arbitration by written notice to the other Party of its intention to arbitrate, and such demand notice shall specify in reasonable detail the nature of the dispute. Each Party shall select one (1) arbitrator, and the two (2) arbitrators so selected shall choose a third arbitrator. All three (3) arbitrators shall serve as neutrals and have at least [***] ([***]) years of: (a) dispute resolution experience (including judicial experience); and/or (b) legal or business experience in the biotech or pharmaceutical industry. In any event, at least one (1) arbitrator shall satisfy the foregoing experience requirement under Clause 20.2(b). Notwithstanding anything to the contrary in this Clause 20.2, in the event of a dispute regarding the Prosecution and Maintenance activities described in Clause 12 at least one (1) arbitrator shall have expertise in patent law. If a Party fails to nominate its arbitrator, or if the Parties' arbitrators cannot agree on the third arbitrator, the necessary appointments shall be made in accordance with the Rules. Once appointed by a Party, such Party shall have no *ex parte* communication with its appointed arbitrator. The arbitration proceedings shall be conducted in [***]. The arbitration proceedings and all pleadings and written evidence shall be in the English language. Any written evidence originally in another language shall be submitted in English translation accompanied by the original or a true copy thereof. Each Party agrees to use commercially reasonable efforts to make all of its current employees available, if reasonably needed, and agrees that the arbitrators may deem any party as "necessary." The arbitrators shall be instructed and required to render a written, binding, non-appealable resolution and award on each issue that clearly states the basis upon which such resolution and award is made. The written resolution and award shall be delivered to the Parties as expeditiously as possible, but in no event more than [***] ([***]) days after conclusion of the hearing, unless otherwise agreed by the Parties. Judgment upon such award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such an award and order for enforcement. [***] The Parties may apply to any court of competent jurisdiction for a temporary restraining order, preliminary injunction or other interim or conservatory relief, as necessary, without breaching these arbitration provisions and without abridging the powers of the arbitrators. At the request of either Party, the arbitrators shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings. The arbitrators shall have the power to decide all questions of arbitrability. The Parties agree that: (i) they shall share equally the fees and expenses of the arbitrators; and (ii) each Party shall bear its own attorneys' fees and associated costs and expenses.

20.3 **Patent validity**

Notwithstanding the other provisions of this Clause 20, any dispute that involves the validity, infringement or claim interpretation of a Patent that is issued: (a) in the United States shall be subject to actions before the United States Patent and Trademark Office and/or submitted exclusively to the federal court located in the jurisdiction of the district where any of the defendants resides; and (b) in any other country shall be brought before an appropriate regulatory or administrative body or court in that country, and the Parties hereby consent to the jurisdiction and venue of such courts and bodies. For the sake of clarity, such Patent disputes shall not be subject to the provisions of Clause 20.2. Nothing in this Agreement shall be construed to prevent the Licensee from disputing or challenging the validity of a Third Party's Patent.

21. **Miscellaneous**

21.1 **General assurances**

At any time after the date hereof each of the Parties shall, at the request and cost of the other Party, execute or procure the execution of such documents and perform or procure the performance of such acts as the other Party may reasonably require for the purpose of giving to the other Party the full benefit of all the provisions of this Agreement, subject to any express restrictions in this Agreement on the extent of either Party's obligations under this Agreement. This includes in particular (without prejudice to the generality of the foregoing) entry into forms of licence or other instruments confirming such rights for registration with appropriate Intellectual Property Offices (including in the form set out in Schedule 4), Regulatory Authorities and other authorities in the Territory.

21.2 **Unenforceability and severability**

If any of the provisions of this Agreement are held to be void or unenforceable, then such void or unenforceable provisions shall be replaced by valid and enforceable provisions that will achieve as far as possible the economic business intentions of the Parties. However, the remainder of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e. the Parties would presumably have concluded this Agreement without the unenforceable provisions.

21.3 **Assignments**

Neither this Agreement nor any of the rights and obligations created herein is assignable or transferable by either Party without the prior written consent of the other, such consent not to be unreasonably withheld or delayed.

Notwithstanding the preceding sentence, each Party is entitled to assign this Agreement and any rights created herein to, subject to the assumption of the obligations herein by, any Affiliate of such Party or any purchaser of the whole or a substantial part of the business of such Party. For the avoidance of doubt, the Parties agree that the Ascendis Platform Technology constitutes a substantial part of the business of Ascendis.

21.4 **Rights cumulative and other matters**

(A) The rights, powers, privileges and remedies provided in this Agreement are cumulative and are not exclusive of any rights, powers, privileges or remedies provided by law or otherwise.

(B) No failure to exercise nor any delay in exercising by any Party to this Agreement of any right, power, privilege or remedy under this Agreement shall impair or operate as a waiver thereof in whole or in part.

(C) No single or partial exercise of any right, power privilege or remedy under this Agreement shall prevent any further or other exercise thereof or the exercise of any other right, powers, privilege or remedy.

21.5 **Costs of preparation**

The Parties hereto shall pay their own respective legal costs incurred in the preparation of this Agreement.

21.6 **Entire Agreement and variation**

(A) This Agreement, together with any documents referred to in it, constitutes the whole agreement between the Parties relating to its subject matter and supersedes and extinguishes any prior drafts, agreements, undertakings, representations, warranties and arrangements of any nature, whether in writing or oral, relating to such subject matter. All information related to the subject matter of this Agreement previously exchanged shall be protected under Clause 10 of this Agreement as if disclosed under this Agreement.

(B) Each Party acknowledges that it has not been induced to enter into this Agreement by any representation or warranty other than those contained in this Agreement and, having negotiated and freely entered into this Agreement, agrees that it shall have no remedy in respect of any other such representation or warranty except in the case of fraud.

(C) No variation of this Agreement shall be effective unless made in writing and signed by each of the Parties.

21.7 **Notices and invoices**

(A) Any notice (which term shall in this Clause 21.7 include any communication) required to be given under this Agreement or in connection with the matters contemplated by it shall, except where otherwise specifically provided, be in writing in the English language.

(B) Any such notice shall be addressed as provided in Clause 21.7(C) and may be:

(1) personally delivered, in which case it shall be deemed to have been given upon delivery at the relevant address if it is delivered not later than 17.00 hours on a Business Day, or, if it is delivered later than 17.00 hours on a Business Day or at any time on a day which is not a Business Day, at 08.00 hours on the next Business Day;

(2) sent by pre-paid registered airmail, or by air courier in which case it shall be deemed to have been given seven (7) Business Days after the date of posting in the case of registered airmail or two (2) Business Days after delivery to the courier, in the case of air courier;

(3) sent by electronic mail, in which case it shall be deemed to have been given when sent from the electronic mail exchange, provided that any notice sent by electronic mail after 17.00 hours on any Business Day or at any time on a day which is not a Business Day shall be deemed to have been given at 08.00 on the next Business Day.

(C) The addresses and other details of the Parties referred to in this Clause 21.7(C) are, subject to Clause 21.7(D):

Ascendis' address:

Ascendis Pharma Bone Diseases A/S
Tuborg Boulevard 5
DK-2900 Hellerup
Denmark

Email: [***]
Attention: [***]

VISEN Pharmaceuticals's address:

VISEN Pharmaceuticals
P.O. Box 472
2nd Floor, Harbour Place
103 South Church Street
George Town, Grand Cayman KY1-1106
Cayman Islands

Email: [***]
Attention: [***]

(D) Either Party to this Agreement may notify the other Party of any change to the address or any of the other details specified in Clause 21.7, provided that such notification shall only be effective on the date specified in such notice or five (5) Business Days after the notice is given, whichever is later.

(E) **Invoices**

All invoices that are required or permitted under this Agreement shall be in writing and sent by Ascendis to the Licensee at the address provided under Clause 21.7(C).

21.8 **Force Majeure**

Neither Party to this Agreement shall be deemed to be in breach of this Agreement or otherwise liable to the other as a result of any delay or failure in the performance of its obligations under this Agreement if and to the extent that such delay or failure is caused by Force Majeure, and the time for performance of the relevant obligation(s) shall be extended accordingly. The Party concerned shall promptly notify the other Party of the nature and effect of such event and both Parties shall, where the same is practicable, use Diligent Efforts to minimise such effect and to comply with the respective obligations herein contained as nearly as may be in their original form, provided that if the Force Majeure event continues for a period of ninety (90) days or more following notification, the Party not affected by the event may terminate this Agreement by giving not less than thirty (30) days prior notice to the other Party.

21.9 **Relationship of the Parties**

(A) Nothing in this Agreement shall constitute, or be deemed to constitute, a partnership between the Parties nor, except as expressly provided, shall it constitute, or be deemed to constitute, any Party the agent of any other Party for any purpose.

(B) Subject to any express provisions to the contrary in this Agreement, neither Party shall have any right or authority to and shall not do any act, enter into any contract, make any representation, give any warranty, incur any liability, assume any obligation, whether express or implied, of any kind on behalf of the other Party or bind the other Party in any way.

21.10 **Counterparts**

This Agreement may be executed in any number of counterparts, which shall together constitute one Agreement. Any Party may enter into this Agreement by signing any such counterpart.

21.11 **Third Party rights**

No person who is not a party to this Agreement shall have any right to enforce any term of this Agreement.

21.12 **Governing law**

This Agreement shall be governed by and construed in accordance with the laws of the state of Delaware, USA, without reference to its conflict of laws principles, and shall not be governed by the United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention).

[Signature page follows]

AS WITNESS the Parties hereof have executed this Agreement the day and year first before written.

Signed by	) /s/ Michael Wolff Jensen
for and on behalf of	) Michael Wolff Jensen, Chairman
ASCENDIS PHARMA	) /s/ Jan Mikkelsen
BONE DISEASES A/S	) Jan Mikkelsen, CEO
Signed by	) /s/ Shan Fu
for and on behalf of	) Shan Fu
VISEN PHARMACEUTICALS	) Director

SCHEDULE 1: ASCENDIS PATENTS

[***]

SCHEDULE 2: ASCENDIS TECHNICAL INFORMATION

1.1 [***]

SCHEDULE 3: EXCLUDED INDICATIONS

[***]

SCHEDULE 4: SHORT FORM PATENT LICENCE

THIS AGREEMENT is made the [ ] day of [ ]

BETWEEN:

(1) **ASCENDIS PHARMA BONE DISEASES A/S**, ("Ascendis"), a company registered in Denmark with its registered office at Tuborg Boulevard 5, DK-2900 Hellerup, Denmark; and

(2) **VISEN PHARMACEUTICALS**, a company registered under the laws of Cayman Islands with its registered address at P.O. Box 472, 2nd Floor, Harbour Place, 103 South Church Street, George Town, Grand Cayman KY1-1106, Cayman Islands.

Ascendis and the Licensee are each a "Party", and together the "Parties", to this agreement.

Ascendis hereby grants to the Licensee an exclusive licence for exploitation of the patent(s) set out in the Appendix below worldwide for the treatment and/or prevention of any disease, condition or disorder of the eye and adnexa, defined according to WHO ICD (but non-exclusive for Diabetic Retinopathy), subject to and terminable in accordance with the terms and conditions of an agreement between the Parties hereto dated [ ].

Appendix

[insert details of relevant patents/patent applications]

AS WITNESS the Parties have executed this agreement the day and year first above written.

Signed by)
for and on behalf of)
ASCENDIS PHARMA)
BONE DISEASES A/S)

Signed by)
for and on behalf of)
VISEN PHARMACEUTICALS)

Exhibit 8.1

Ascendis Pharma A/S

Subsidiaries of the Registrant

Name	Jurisdiction of Incorporation
Ascendis Pharma GmbH	Germany
Ascendis Pharma, Inc.	Delaware, USA
Ascendis Pharma, Endocrinology Division A/S	Denmark
Ascendis Pharma, Ophthalmology Division A/S	Denmark
Ascendis Pharma Bone Diseases A/S	Denmark
Ascendis Pharma Growth Disorders A/S	Denmark

Exhibit 12.1

CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jan Møller Mikkelsen, certify that:

1. I have reviewed this annual report on Form 20-F of Ascendis Pharma A/S (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a 15(f) and 15d 15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: April 3, 2019

By: /s/ Jan Møller Mikkelsen
Name: Jan Møller Mikkelsen
Title: Chief Executive Officer

Exhibit 12.2

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott T. Smith, certify that:

1. I have reviewed this annual report on Form 20-F of Ascendis Pharma A/S (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a 15(f) and 15d 15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: April 3, 2019

By: /s/ Scott T. Smith
Name: Scott T. Smith
Title: Chief Financial Officer and Principal Financial Officer

Exhibit 13.1

CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002*

In connection with the Annual Report on Form 20-F of Ascendis Pharma A/S (the "Company") for the year ended December 31, 2018, as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Jan Møller Mikkelsen, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 3, 2019

By: /s/ Jan Møller Mikkelsen
Name: Jan Møller Mikkelsen
Title: Chief Executive Officer

Exhibit 13.2

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002*

In connection with the Annual Report on Form 20-F of Ascendis Pharma A/S (the "Company") for the year ended December 31, 2018, as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Scott T. Smith, as Chief Financial Officer and Principal Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 3, 2019

By: /s/ Scott T. Smith
Name: Scott T. Smith
Title: Chief Financial Officer and Principal Financial Officer

Deloitte.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-203040, 333-210810, 333-211512, 333-213412, 333-214843, 333-216883 and 333-228576 on Form S-8 and Registration Nos. 333-209336, 333-211511, 333-216882, 333-223134 and 333-225284 on Form F-3 of our reports dated April 3, 2019, relating to the consolidated financial statements of Ascendis Pharma A/S and subsidiaries, and the effectiveness of Ascendis Pharma A/S and subsidiaries' internal control over financial reporting, appearing in this Annual Report on Form 20-F of Ascendis Pharma A/S for the year ended December 31, 2018.

/s/ Deloitte Statsautoriseret Revisionspartnerselskab
Copenhagen, Denmark
April 3, 2019

/s/ Henrik Kjelgaard
State-Authorised Public Accountant

/s/ Max Damborg
State-Authorised Public Accountant