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, 2020

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)

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(Address of principal executive offices)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares, each representing one ordinary share, nominal value DKK 1 per share	**ASND**	**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

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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:

53,750,386 ordinary shares
(as of December 31, 2020)

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

Note – Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

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 every Interactive Data File required to be submitted 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 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 that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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	1
Special Note Regarding Forward-Looking Statements	1
PART I	4
Item 1 Identity of Directors, Senior Management and Advisers	4
Item 2 Offer Statistics and Expected Timetable	4
Item 3 Key Information	4
Item 4 Information on the Company	62
Item 4A Unresolved Staff Comments	108
Item 5 Operating and Financial Review and Prospects	109
Item 6 Directors, Senior Management and Employees	123
Item 7 Major Shareholders and Related Party Transactions	136
Item 8 Financial Information	140
Item 9 The Offer and Listing	140
Item 10 Additional Information	141
Item 11 Quantitative and Qualitative Disclosures About Market Risk	161
Item 12 Description of Securities Other than Equity Securities	161
PART II	162
Item 13 Defaults, Dividend Arrearages and Delinquencies	162
Item 14 Material Modification to the Rights of Security Holders and Use of Proceeds	162
Item 15 Control and Procedures	163
Item 16A Audit Committee Financial Expert	164
Item 16B Code of Ethics	164
Item 16C Principal Accountant Fees and Services	164
Item 16D Exemptions from the Listing Standards for Audit Committees	164
Item 16E Purchases of Equity Securities by the Issuer and Affiliated Purchasers	164
Item 16F Change in Registrants Certifying Accountant	165
Item 16G Corporate Governance	165
Item 16H Mine Safety Disclosure	165
PART III	166
Item 17 Financial Statements	166
Item 18 Financial Statements	166
Item 19 Exhibits	II-1

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, or IFRS, as issued by the International Accounting Standards Board, or IASB. All references in this annual report to “Dollars”, “USD” and “$” are to U.S. Dollars, and all references to “euro”, “EUR” 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:

- the timing or likelihood of regulatory filings and approvals for our product candidates, including our expectations regarding approval of our Biologics License Application and Marketing Authorization Application for TransCon Growth Hormone, or TransCon hGH or lonapegsomatropin (the adopted nonproprietary name for TransCon hGH), lonapegsomatropin for the treatment of pediatric GHD;
- the scope, progress, results and costs of developing our product candidates or any other future product candidates, and conducting preclinical studies and clinical trials;
- our pursuit of oncology as our second of three independent therapeutic areas of focus, and our development of a pipeline of product candidates related to oncology;
- 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 similar 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 similar 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 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 technologies;
- 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;
- developments and projections relating to our competitors and our industry; and
- the effects on our business of the worldwide COVID-19 pandemic.

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—Key Information—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.

Summary of Material Risks Associated with Our Business

The principal risks and uncertainties affecting our business include the following:

- The global pandemic caused by COVID-19 could materially adversely impact our business, including our clinical trials, supply chain operation, regulatory timelines and commercial activities.
- 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 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.
- 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.
- Clinical drug development involves a lengthy and expensive process with uncertain outcomes, 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.

- Interim, “topline” and preliminary data from our clinical trials that we 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.
- We have limited direct sales and distribution capabilities and no sales experience with any of our own product candidates and we may not be able to successfully commercialize any of our product candidates.
- 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.
- 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.
- Our operating results may vary significantly from period to period and these variations may be difficult to predict.
- 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.
- The regulatory approval processes of the U.S. Food and Drug Administration, the European Medicines Agency 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.
- 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.

The summary risk factors described above should be read together with the text of the full risk factors below in the section entitled “Risk Factors” and the other information set forth in this Annual Report on Form 20-F, including our consolidated financial statements and the related notes, as well as in other documents that we file with the U.S. Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

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. Reserved.

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, or 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 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 the preparation for potential commercialization of TransCon Growth Hormone, or lonapegsomatropin, if approved, and, in particular, developing our lead product candidates, lonapegsomatropin, TransCon Parathyroid Hormone, or TransCon PTH, TransCon C-Type Natriuretic Peptide, or TransCon CNP, our product candidates in oncology 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. Going forward, we may incur significant losses from our operations. We had a net loss of €419.0 million during the year ended December 31, 2020 and a net loss of €218.0 million during the year ended December 31, 2019. Our total equity was €838.7 million as of December 31, 2020 compared to €597.1 million as of December 31, 2019. 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 collaboration partners or begin receiving revenue from commercial product sales, we may incur substantial operating losses for the foreseeable future as we execute our operating plan.

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 commercial product sales.

We have no products approved for sale and have never generated any revenue from commercial product sales. Our ability to generate revenue from commercial product sales depends on our ability 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. Our ability to generate future revenue from commercial product sales or pursuant to milestone payments or royalties from 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;
- our ability to commercialize or co-promote, and/or the ability of our collaboration partners to successfully commercialize, 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 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 commercial product sales or pursuant to up-front or milestone payments and royalties from 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 collaboration agreements. For example, in July 2020, we received $654.6 million (€580.5 million) in net proceeds from a public offering of American Depositary Shares representing our ordinary shares after deducting the underwriting commissions and offering expenses. As of December 31, 2020, we had marketable securities and cash and cash equivalents totalling €834.1 million. We believe that we will continue to expend substantial resources for the foreseeable future, including costs associated with research and development, preparing for potential commercialization, 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, 2020 will be sufficient to meet our projected cash requirements for at least the twelve 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:

- 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;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to collect payments which are due to us from collaboration partners (if any), which in turn is impacted by the financial standing of any such 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 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;
- the achievement of development, regulatory and commercial milestones resulting in the payment to us from collaboration partners of contractual milestone payments and the timing of receipt of such payments, if any; our progress 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, preparing for potential commercialization, 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 issuance of 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. Our near-term prospects, including our ability to generate revenue from commercial 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 lonapegsomatropin, TransCon PTH and TransCon CNP;
- our ability and that of any collaboration partners to establish and maintain 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 will require additional clinical trials prior to approving our product candidates, if ever;
- 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 any 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 lonapegsomatropin 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 and any collaboration partners' marketing, sales and distribution strategies and operations;
- our ability and that of any collaboration partners, or any third-party manufacturer we 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 any collaboration partners.

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 any 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 uncertain outcomes, 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 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:

- generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials
- obtain regulatory authorization to commence a trial;
- 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, or ethics committee approval at each site;
- manufacture, test, release, validate or import sufficient quantities of drug product for use in a trial;
- recruit, screen and enroll 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; or
- initiate or add a sufficient number of clinical trial sites.

The novel Coronavirus (COVID-19) pandemic has had, and may continue to have an evolving impact on the conduct of clinical trials of investigational therapeutic candidates, and any challenges which may arise, for example, from quarantines, site closures, travel limitations, interruptions to the supply chain for our product candidates, or other considerations if site personnel or trial subjects become infected with COVID-19, which may lead to difficulties in meeting protocol-specified procedures, including administering or using the therapeutic candidate or adhering to protocol-mandated visits and laboratory/diagnostic testing, unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures, which will likely vary depending on many factors, including the nature of disease under study, the trial design, and in what region(s) the study is being conducted.

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 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, and plan to conduct, clinical trials in sites outside of the United States. 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 establish 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 commercial 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 commercial 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 certain collaboration partners to develop and conduct clinical studies with, obtain regulatory approvals for, market and sell 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 of such product candidates would be significantly reduced and our business would be significantly harmed.

We rely on our collaboration partners to conduct certain clinical studies. For example, in November 2018, we announced the formation of VISEN Pharmaceuticals, or 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 may also enter into collaboration agreements with other parties in the future relating to our other product candidates.

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. 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; and
- 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.

In particular, VISEN may terminate in the event of our bankruptcy or insolvency.

The timing and amount of any milestone and royalty payments we may receive under agreements with collaboration partners and the value of any equity we own in our collaboration partners (such as the equity we own in VISEN) 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 development and regulatory milestones will be achieved or that we will receive any future milestone payments under agreements we may enter into with collaboration partners. 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 also cannot be certain that any equity we own in our collaboration partners (such as the equity we own in VISEN) will maintain its value or grow in value.

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 product candidates 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.

Certain of our product candidates 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. Certain of our product candidates are in preclinical development and may require significant time and additional research and development before we can file INDs or equivalent foreign regulatory filings 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 commercial product sales in future periods or achieve or sustain profitability.

Interim, "topline" and preliminary data from our clinical trials that we 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 publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data 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, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

By expending our limited resources to pursue particular product candidates and areas of focus we may fail to capitalize on product candidates or areas of focus that are more profitable or for which there is a greater likelihood of success.

We have focused on research programs and product candidates on the endocrinology and oncology therapeutic areas of focus. As a result, we may forego or delay pursuit of opportunities with other product candidates or in other focus areas 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 lonapegsomatropin, 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 any collaboration partners, or trials we conduct with our 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 any 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. For example, in June 2020, we submitted a BLA to the FDA for approval of lonapegsomatropin for the treatment of pediatric GHD. In our discussions with the FDA relating to this BLA submission to date, the FDA has indicated that it has not identified significant safety issues and a REMS is not currently being considered for lonapegsomatropin, if approved; however, the FDA's review of this BLA submission is ongoing and the FDA may still require us to adopt a REMS for lonapegsomatropin for the treatment of GHD.

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 any 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 any 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 any 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. To our knowledge, as of the date of this report, there are no commercially available long-acting growth hormone treatment options 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. On August 28, 2020, the FDA granted Novo Nordisk Inc. approval of somapacitan for replacement of endogenous growth hormone in adult patients with GHD but as of the date of this report to our knowledge Novo Nordisk has not commercially launched the product in the United States. In January 2021, Novo Nordisk received a positive opinion from the Committee for Medicinal Products for Human Use, under the EMA for once-weekly somapacitan, recommending marketing authorisation for use in adult patients with GHD. Pfizer (in collaboration with OPKO Health Inc.) has submitted to the FDA, a Biologics License Application, or BLA, for somatrogon, a long-acting growth hormone for the treatment of pediatric patients with GHD. In January 2021, Pfizer (in collaboration with OPKO Health) announced the FDA has accepted the regulatory submission and set the PDUFA goal date in October 2021. Other experimental growth hormone therapies based on permanent modification are in different stages of clinical development by various companies, including GeneScience Pharmaceuticals Co., Ltd., Genexine Inc., I-MAB, and JCR Pharmaceuticals Co., Ltd. In addition, Shire plc owns the rights to Natpara, a treatment for hypoparathyroidism. Natpara was voluntarily recalled in September 2019 in the U.S. and is now only available to a limited number of patients through a Special Use Program offered by its manufacturer, Takeda Pharmaceutical Company. 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, Amolyt Pharma, and Eli Lilly and Company. Other companies are developing therapies for achondroplasia, including BioMarin, Pfizer, QED Therapeutics and BioClin Therapeutics. BioMarin Pharmaceutical, Inc. is developing vosoritide for the treatment of achondroplasia, and Therachon and BioClin Therapeutics, Inc. are developing compounds for achondroplasia. Other companies are developing toll like receptor agonists for cancer immunotherapy including: Nektar Therapeutics, CureVac N.V., Seven and Eight Biopharmaceuticals Inc., Idera Pharmaceuticals, Inc., Checkmate Pharmaceuticals, Inc., Exicure, Inc., Bolt Therapeutics, Inc., and Silverback Therapeutics, Inc. 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 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.

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 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 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 develop product candidates based on these novel technologies, and we intend 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 any collaboration partners develop using our novel technologies would adversely affect our business.

We have limited clinical data on product candidates utilizing our TransCon technologies 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 any 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 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 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. In the European Union, 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 a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Orphan drug designation must be requested before submitting a BLA or NDA in the United States or an MAA in Europe.

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. The applicable exclusivity period is ten years in the European Union ("EU"), but such exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

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 for the treatment of hypoparathyroidism, in February 2019, we were granted orphan drug designation by the FDA for TransCon CNP for the treatment of achondroplasia, and in April 2020, we were granted orphan drug designation by the FDA for lonapegsomatropin for the treatment of GHD. Additionally, in August 2020, we were granted orphan designation by the European Commission for TransCon CNP for the treatment of achondroplasia and in October 2020, we were granted orphan designation by the European Commission for TransCon PTH for Treatment of hypoparathyroidism. In October 2019, we were granted orphan designation by the European Commission for lonapegsomatropin for GHD. However, we may be unsuccessful in obtaining orphan drug designation or orphan 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 granted orphan exclusivity and approved, the FDA can subsequently approve a later application for the same drug for the same condition before the expiration of the seven-year exclusivity period 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 biological product for which we intend to seek approval may face competition sooner than anticipated.

The Affordable Care Act, or the ACA, 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 biological product candidates approved 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 have limited direct sales and distribution capabilities and no sales experience with any of our own product candidates and we may not be able to successfully commercialize any of our product candidates.

We have limited direct sales and distribution capabilities and no sales experience with any of our own product candidates. 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 have a limited sales organization and have no sales experience with any of our own product candidates. To commercialize any of our product candidates, we or any 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 any 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 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 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 any collaboration partners will need to secure sufficient manufacturing capacity with third-party manufacturers. If we and/or any 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. For example, public health epidemics or pandemics, such as the novel coronavirus disease (COVID-19) currently impacting multiple jurisdictions worldwide may impact the ability of our existing or future manufacturers to perform their obligations under our manufacturing agreements with such parties. Such failure or substantial delay could materially harm our business. To be successful, our product candidates must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. We and/or any 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 any 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 any collaboration partners may encounter problems with aspects of manufacturing 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 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, 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 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 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 VISEN, we are obligated to use commercially reasonable efforts to supply clinical trial material for VISEN to conduct certain clinical trials, 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.

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 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.

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 judgements 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 $40 million in the aggregate on our excess insurance policy. Any claim that may be brought against us could result in a court judgement 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, 2020, we had 482 full-time employees worldwide, with key facilities in Denmark, Germany, and the United States. As we 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 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 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. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting, and 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, 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 collaboration agreements, if any;
- the introduction of new products and services by us, 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, if any.

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. 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 EU could harm our business in the future. Despite measures taken by the European Union to provide funding to certain EU 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 EU member states. The effects on our business of a potential dissolution of the European Union, the exit of one or more EU. 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 withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

Following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdrew from the European Union and ratified a trade and cooperation agreement governing its future relationship with the European Union. The agreement, which was applied provisionally from January 1, 2021 until it is ratified by the European Parliament and the Council of the European Union, addresses trade, economic arrangements, law enforcement, judicial cooperation and a governance framework including procedures for dispute resolution, among other things. Because the agreement merely sets forth a framework in many respects and will require complex additional bilateral negotiations between the United Kingdom and the European Union as both parties continue to work on the rules for implementation, significant political and economic uncertainty remains about how the precise terms of the relationship between the parties will differ from the terms before withdrawal.

These developments, or the perception that any related developments could occur, have had and may continue to have a material adverse effect on global economic conditions and financial markets, and may significantly reduce global market liquidity, restrict the ability of key market participants to operate in certain financial markets or restrict our access to capital. Any of these factors 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 work conducted by these distributors;
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the FCPA, its books and records provisions, or its anti-bribery provisions; 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 lonapegsomatropin drug substance are supplied by Fujifilm Diosynth Biotechnologies UK Limited, or Fujifilm, pursuant to our agreement with Fujifilm. lonapegsomatropin drug product in vials is manufactured by Vetter Pharma Fertigung, or Vetter, pursuant to our agreement with Vetter. lonapegsomatropin drug product in dual chamber cartridges will be supplied by Vetter 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 lonapegsomatropin to methoxy PEG, or 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. Vetter manufactures the TransCon PTH drug product in cartridges and assembles the cartridges with a drug delivery device made by Ypsomed AG. CNP drug substance is supplied by Wacker Biotech, Germany. Our TransCon CNP drug product in vials is manufactured by Vetter pursuant to our agreement with Vetter. With the exception of Lonza, who will be supplying Transcon hGH drug substance, we do not currently have any other suppliers for the drug substance, drug product or other components of our product candidates for lonapegsomatropin, 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 result in delays in product development and harm our business.

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. In addition, we could experience difficulties attracting and retaining qualified employees 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. 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, telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. 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.

The global pandemic caused by COVID-19 could materially adversely impact our business, including our clinical trials, supply chain operation, regulatory timelines and commercial activities.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has been declared by WHO to be a worldwide pandemic. As a result of the rapidly growing spread of COVID-19 throughout the areas we operate, we may experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials, which could potentially have a negative impact on clinical trial timelines;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- significant increases in expenses required to manage impacts to our business to complete our planned operations within our projected timelines;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;

- interruption in global shipping that may affect the transport of clinical trial materials, such as comparator drugs used in certain of our clinical trials;
- interruptions in our global supply chain with regards to clinical trial and potential commercial grade material;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of regulatory authorities to accept data from clinical trials in these affected geographies.
- in conducting our clinical trials, suppliers may experience delays in providing necessary equipment, consumables and services, which potentially could cause temporary delays in clinical trial activities;
- global demand for COVID-19 vaccines could result in contract manufactures not having sufficient capacity to meet scheduled manufacturing. In addition, sourcing of certain types of raw materials, consumables and equipment could result in scheduled manufacturing being delayed or postponed;
- travel restrictions and local outbreaks of COVID-19 could restrict authorities from performing site inspections in connection with their review procedures of marketing applications for lonapegsomatropin, which could potentially delay the commercial launch; and
- our commercial launch strategy, including for lonapegsomatropin, could be negatively impacted by patients not being able to see their physicians, and similarly, our commercial team not being able to meet with physicians, which could both have a negative impact on the commercial launch strategy.

In addition, the pandemic has caused, and is likely to cause further, disruption to global financial markets. This may reduce our ability to access capital on favorable terms or to access capital at all. Furthermore, sustained adverse market events (such as a recession or depression) resulting from the pandemic could materially and adversely affect our business and the price of our ADSs.

The extent to which the COVID-19 coronavirus further impacts our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the speed and extent of geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the affected areas, business closures or business disruptions and the effectiveness of actions taken in the affected areas to contain and treat the disease.

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, EU legislative bodies and other regulatory authorities in the United States, the EEA and other jurisdictions, which regulations differ from country to country. We are not permitted to market any drug product in the United States until we receive marketing approval from the FDA. Equally, we are not permitted to market any drug product in the EEA until we receive a marketing authorization from the EMA or EEA Member State Competent Authorities. In September 2020, the FDA filed our BLA for lonapegsomatropin for the treatment for pediatric GHD for substantive review and set a target action date of June 25, 2021, and in September 2020, we submitted a marketing authorization application to the EMA for lonapegsomatropin for the treatment of pediatric hormone growth deficiency. We have not submitted an application or obtained marketing approval for any of our other 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 biological product candidate in the United States, the EEA or other regions, we 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 biological product 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 biological product candidates 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 any 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 an NDA or BLA, marketing authorization application, or other submission or to obtain regulatory approval in the United States, the EEA or elsewhere;
- we, or any 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 lonapegsomatropin, TransCon PTH, TransCon CNP, or any of our other product candidates in the United States, the EMA or in any other jurisdiction. In June 2020, we submitted a BLA with the FDA for lonapegsomatropin, for the treatment for pediatric GHD. In September 2020, the FDA filed our BLA for lonapegsomatropin for substantive review and set a target action date of June 25, 2021, and in September 2020, we submitted a marketing authorization application to the EMA for lonapegsomatropin for the treatment of pediatric hormone growth deficiency We have yet to submit an NDA to the FDA for TransCon PTH, TransCon CNP, or any of our other product candidates. We have yet to submit a Marketing Authorization Application, or MAA, to the EMA, national regulatory authorities in Europe or to any international regulatory authorities for TransCon PTH, TransCon CNP, or any of our other 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 any of our other 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.

We have developed 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 have developed an auto-injector with Phillips Medisize A/S (formerly Medicom Innovation Partner A/S) to facilitate the administration of lonapegsomatropin by patients. In addition, we have developed 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 lonapegsomatropin and TransCon PTH. Because of our auto-injector and TransCon PTH drug delivery device, the FDA's review of lonapegsomatropin 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 lonapegsomatropin 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, recordkeeping, 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 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. In addition, as part of a review process, the FDA may refer an application for a novel drug or biologic to an advisory committee to review, evaluate and provide a recommendation as to whether the application should be approved and

under what conditions. At the time of our mid-cycle review with the FDA relating to our BLA submitted to the FDA for approval of lonapegsomatropin for the treatment of pediatric GHD, the FDA indicated that it had no plans for an Advisory Committee Meeting for our BLA submission; however, there can be no assurance that the FDA will not convene an Advisory Committee Meeting relating to our BLA submission. If we 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 develop;
- impose costly procedures on us or any collaboration partners;
- diminish any competitive advantages in the marketplace that we or any 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, any 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, any 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 recordkeeping of our products. If we or any 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 (or, under FDA guidance, consistent with) 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 lonapegsomatropin. 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 many 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. Certain payments and other transfers of value to U.S. licensed physicians (as defined under statute) and teaching hospitals must be reported under the Physician Payments Sunshine Act. 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 laws or regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, the results of the 2020 U.S. Presidential Election may impact our business and industry. Namely, the Trump administration took 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 whether or how these orders will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulations governing 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 be subject to enforcement action and we may not 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, off-label promotion of medicinal products is not permitted. Furthermore, advertising to the general public of medicinal products which are available on medical prescription only is prohibited. The requirements are regulated by both EU regulations (such as advertising of medicinal products and reporting of adverse events) as well as national applicable regulations (namely related to prices and promotional activities).

The regulatory requirements relating to the manufacturing, testing, marketing and sale of pharmaceutical products are subject to periodic change. This may impact our ability 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.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. 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, medical devices and biologics or modifications to approved 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.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. For example, in connection with the FDA's review of our BLA submission for approval of lonapegsomatropin for the treatment of pediatric GHD, the FDA has indicated a desire to conduct an on-site inspection of certain manufacturing facilities in the United Kingdom. We have discussed with the FDA alternatives for inspection if restrictions imposed due to the COVID-19 pandemic prevent an on-site inspection of the facility in the United Kingdom. However, if the FDA determines it needs to conduct an on-site inspection of certain manufacturing facilities, such as the manufacturing site in the United Kingdom, to approve lonapegsomatropin for the treatment of pediatric GHD, the COVID-19 pandemic could delay approval until an on-site inspection is completed.

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. Many countries, including the European Union member

states, established complex and lengthy procedures to obtain price approvals, coverage and reimbursement. These procedures vary from country to country but are commonly initiated after grant of the related marketing authorization. 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. As an example, many EU member states review periodically their decisions concerning the pricing and reimbursement of medicinal products. The outcome of these reviews cannot be predicted and could have adverse effects on the pricing and reimbursement of our medicinal products in the EU member states.

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 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 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 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 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. Furthermore, interruption or delay in supplies from one contract manufacturer may cause delays further down the supply chain, as certain contract manufacturers may rely on delivery of materials from other contract manufacturers.

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, as well as courts. If any of our product candidates receives marketing approval, we will be restricted from marketing the product outside of its approved labeling, also referred to as promotion. However, physicians may nevertheless lawfully 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 and other illegal promotional activities. 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.

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.

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, 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.

Additionally, our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and, therefore, involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA.

There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these requirements. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective 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 comply with these requirements. 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.

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, 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 ten-year period of market exclusivity is extended to twelve years.

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;
- 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. 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 Act;
- 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;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; 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 in order to have committed a violation;
- the U.S. federal Physician Payments Sunshine 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers beginning in 2022, and teaching hospitals, and ownership and investment interests held by physicians (as defined under statute) 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
- European and other foreign law equivalents of each of the laws, including regulation regarding advertising of medicinal products and 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 activities 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 significant 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 and/or EEA healthcare programs and imprisonment, any of which could adversely affect our ability to market our products and adversely impact our financial results.

Changes in and failures to comply with U.S. and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention and security of personal data, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. Complying with these numerous, complex and often changing regulations is expensive and difficult, and any failure or perceived failure to comply with any data privacy laws or security laws, our policies and procedures, our contracts governing our processing of personal information 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 partners or another third-party, could adversely affect our business, financial condition and results of operations, and could result in negative publicity, government investigations and enforcement actions, claims by third-parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws

and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, California enacted the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act, or the CPRA, recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In Europe, the General Data Protection Regulation, or the GDPR imposes strict requirements for processing the personal data of individuals within the EEA, including clinical trial data. For example, the GDPR requires us to make 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 and in other cases prevents the use of consent as legal basis for processing of personal data, requires the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides robust rights for data subjects, imposes mandatory data breach notification through the EU and EEA, 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. The law in this area is also developing rapidly. For example, in July 2020, the Court of Justice of the EU invalidated the Privacy Shield, limiting how organizations could lawfully transfer personal data from the EEA to the U.S. Relatedly, following the United Kingdom's withdrawal from the EEA and the EU, and the expiry of the transition period, companies have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. 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.

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 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 ACA 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 ACA, 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, was 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.

Since its enactment, there have been judicial, executive and Congressional challenges to certain provisions of, the ACA. For example, the Tax Cuts and Jobs Act, enacted on December 22, 2017, removes penalties for not complying with the ACA’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 because the individual mandate is a critical and inseverable feature of the ACA, the remaining provisions of the ACA were invalid as well. Upon appeal, the U.S. Court of Appeals for the Fifth Circuit affirmed that the individual mandate was unconstitutional but remanded the case back to the U.S. District Court to determine what portions of the ACA, if any, might continue to be valid. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts to challenge, repeal or replace the ACA, if any, will impact the law. 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 ACA was enacted, including reductions in Medicare payments to providers, capped at 2% per fiscal year, which went into effect on April 1, 2013. These reductions, extended by subsequent legislation will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012 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, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. The current presidential administration has offered multiple proposals and plans as means to lower drug costs. Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. The likelihood of implementation of any of these reform initiatives is uncertain, particularly in light of the new Presidential administration. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including through constraints on reimbursement, imposition of mandatory discounts, discounts, restrictions on access to certain products, transparency measures, and programs for importation from other countries or 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, 2020, 28 patents have been issued to us in the United States. 17 patents are directed to our TransCon technologies and five are directed to TransCon hGH. In addition, as of December 31, 2020, we have approximately 170 issued patents in jurisdictions outside of the United States, at least 89 of which are directed to our TransCon technologies, and 43 of which are directed to our product candidates. As of December 31, 2020, our TransCon hGH is covered by seven different patent families and an additional nine patent families covering the auto injector device, our TransCon PTH is covered by nine different patent families and our TransCon CNP is covered by eleven 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, including due to the impact of the COVID-19 pandemic on our or our licensors' business operations, 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 harm our business. Further, patents have a limited lifespan. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. If we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

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 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.

We license intellectual property rights from third-parties. Such licenses may be subject to early termination if we fail to comply with our obligations in our licenses with third-parties, which could result in the loss of rights or technology that are material to our business.

We are or may become a party to licenses that give us rights to third-party intellectual property or technology that is necessary or useful for our business, and we may enter into additional licenses in the future. Under these license agreements, we are or may become obligated to pay the licensor fees, which may include annual license fees, milestone payments, royalties, a percentage of revenues associated with the licensed technology and a percentage of sublicensing revenue. These fees may be significant, which could make it difficult for us to achieve or maintain profitability. In addition, under certain of such agreements, we are or may become required to diligently pursue the development of products using the licensed technology. If we fail to comply with these obligations, including due to the impact of the COVID-19 pandemic on our business operations or our use of the intellectual property licensed to us in an unauthorized manner, and fail to cure our breach within a specified period of time, the licensor may have the right to terminate the applicable license, in which event we could lose valuable rights and technology that are material to our business, harming our ability to develop, manufacture and/or commercialize our platform or product candidates.

In addition, the agreements under which we license intellectual property or technology to or from third-parties can be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. If we fail to obtain in-license any compositions, methods of use, processes or other third-party intellectual property rights at a reasonable cost or on reasonable terms, we could harm our business. If we fail to obtain licenses to necessary third-party intellectual property rights, we may need to cease use of the compositions or methods covered by such third-party intellectual property rights. Furthermore, we may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

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. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. 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 anticipated product launch, (ii) are invalid, and/or (iii) do not and will not cover our product or device. Additionally, we are aware of an allowed patent application owned by a competitor related to macromolecules capable of releasing CNP variants and methods of treating various disorders including achondroplasia using such macromolecules. Although we believe that these allowed claims are invalid, we could be wrong in our assessment. We cannot be certain that our product candidates will not infringe these or other existing or future patents. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Additionally, 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. 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. Nevertheless, we are not aware of any valid issued patents that we believe would prevent us from marketing our product candidates, if approved.

In addition, we may face costly and time-consuming intellectual property litigation with the NDA holders, BLA 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 and BLA 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 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 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. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings and some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. 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 patent applications and the enforcement or defense of our 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, 2020, 96 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. Although an inadvertent lapse, including due to the effect of the COVID-19 pandemic on us or our patent maintenance vendors, can in many cases

be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which 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.

Failure to secure trademark registrations for a commercial trade name for any of our product candidates in the United States or elsewhere could adversely affect our business.

We use various trademark rights in our business, including, Ascendis, and our trade name TransCon. Ascendis and TransCon are our only registered trademarks in the United States. A trademark application for lonapegsomatropin has been filed in the United States and the European Union. However, our current or future trademarks and trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks, and 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 other 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. We may license our trademarks and trade names to third-parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

As a result of the United Kingdom’s exit from the European Union, our trademarks in the European Union are 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 trademarks in the UK.

Moreover, any name we propose to use with our product candidates in the United States or any other country must be approved by the FDA, EMA or any other relevant health authority regardless of whether we have registered it, or applied to register it, as a trademark. The FDA as well as EMA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA, EMA or any other relevant approval authority 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, EMA or any other relevant approval authority.

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

Patents are of national or regional effect, and 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. For example, patents with claims directed to dry pharmaceutical formulations of TransCon hGH have issued in the United States, Europe, and other jurisdictions, but related claims were rejected in China. This decision is currently on appeal, and we intend to vigorously defend the patentability of these claims. However, we may be unsuccessful, and our patent protection for TransCon hGH may expire sooner in China than in other jurisdictions. 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 certain 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.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators, or other third-parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third-parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We or our licensors may have relied on third-party consultants or collaborators or on funds from third-parties, such as national governments, such that we or our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third-parties have ownership rights or other rights to our patents, including in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Risks relating to our ordinary shares and ADSs

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

The trading price of the 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:

- results from, or any delays in, clinical trial programs relating to our product candidates, including clinical trials for lonapegsomatropin, TransCon PTH and TransCon CNP;
- the effects on our business, operating results, prospects and financial condition of the worldwide COVID-19 pandemic;
- 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;
- 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 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 ordinary 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.

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.

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 representing our ordinary shares in the public market, the trading price of our ADSs could decline. If our outstanding warrants are exercised additional 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, 2021, our senior management, board members, holders of 5% or more of our share capital and their respective affiliates beneficially own approximately 68.6% of our outstanding voting securities. See "Item 7 A. Major Shareholders" for information relating to the determination of the number of shares beneficially owned by an entity or a person. 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.

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 judgements 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 judgements, other than arbitration awards, in civil and commercial matters. Consequently, a final judgement 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 judgement which is enforceable in Denmark, the party in whose favor a final and conclusive judgement 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 judgement 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 judgement of the U.S. court, unless such judgement 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 judgements of U.S. courts in Denmark are solely governed by the provisions of the Danish Administration of Justice Act.

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 judgements obtained in U.S. courts in civil and commercial matters, including judgements 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 large accelerated filers are required to file their annual report on Form 10-K within 60 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 and as adopted by the European Union. 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 permits 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 The 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, 2021, 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, 2022. 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 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.

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 performance of the ADSs, or if our clinical trials and operating results fail to meet the expectations of analysts, the price of the 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 the ADSs or trading volume to decline.

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. Based on the market price of our ADSs, the value of our assets and the 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, 2020. 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 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 (generally 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 "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. Although we do not believe we were a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2020, the application of the PFIC rules is subject to uncertainty in several respects. Whether we will be a PFIC in any year depends on the composition of our income and assets, and the relative fair market value of our assets from time to time, which we expect may vary substantially over time. Among other things, because (i) we currently own a significant amount of passive assets, including cash, and (ii) the value of our assets (including our intangible assets) that generate non-passive income for PFIC purposes is uncertain and may vary substantially over time, we cannot assure you we will not be a PFIC for any tax year. 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. Failure to comply with these reporting obligations may subject a "United States shareholder" to significant monetary penalties and may prevent the statute of limitations from starting with respect to such shareholder's U.S. federal income tax return for the year for which reporting was due. Further, 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. 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.

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 corporate 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 two product candidates identified in oncology, our second therapeutic area of focus. We are also working to apply our TransCon technologies in additional therapeutic areas to address unmet patient needs.

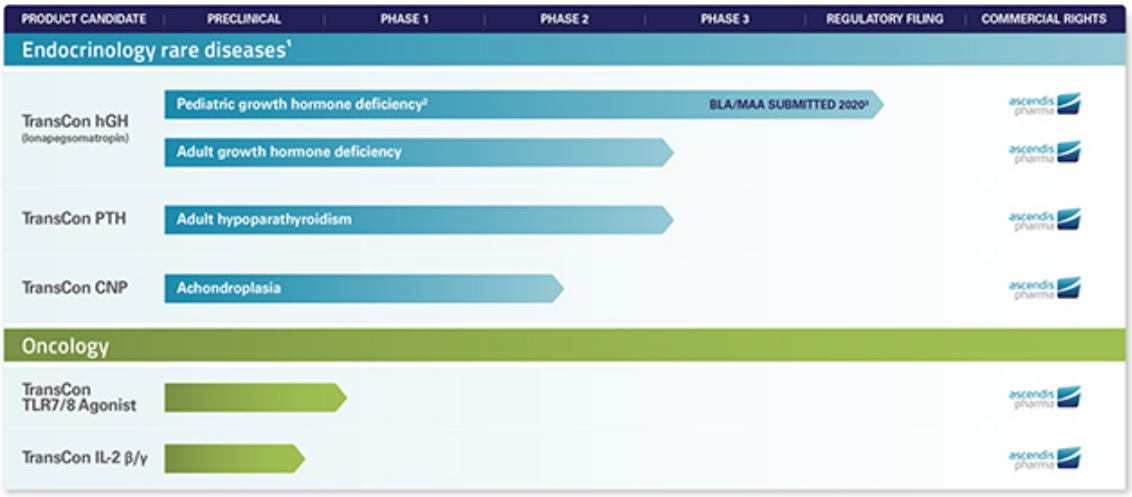
Our most advanced investigational product candidate, TransCon Growth Hormone, or TransCon hGH or lonapegsomatropin (the adopted nonproprietary name for TransCon hGH), is currently under regulatory review by the Food and Drug Administration, or the FDA in the U.S. and European Medicines Agency in Europe as a once-weekly long-acting prodrug of recombinant human growth hormone, also referred to as somatropin or hGH, as a potential treatment for pediatric growth hormone deficiency, or GHD.

We are also using our TransCon technologies to develop other product candidates to address rare endocrine diseases. These product candidates include TransCon PTH as a potential treatment for adult hypoparathyroidism and TransCon CNP as a potential therapeutic option for achondroplasia, the most common form of dwarfism.

In addition to our pipeline of candidates in rare endocrine diseases, in January 2019, we disclosed 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 our TransCon technologies to clinically validated drugs, using our unique algorithm for product innovation. 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. In December 2020, we submitted an investigational new drug application, or IND, to the FDA to initiate the clinical program of TransCon TLR7/8 Agonist, a long-acting prodrug of resiquimod, a small molecule agonist of Toll-like receptors (TLR) 7 and 8. TransCon IL-2 b/g, our second oncology product candidate, is currently in preclinical development.

We believe that the effectiveness of our TransCon technologies is supported by data from our preclinical research and the ongoing clinical programs, including our lonapegsomatropin, TransCon PTH and TransCon CNP programs, as well as findings from our ongoing development of other product candidates. We have applied our TransCon technologies in combination with a clinically validated parent drug or pathway using our algorithm for creating products with the potential to be best-in-class in endocrinology rare diseases, and we plan to apply this algorithm for product selection in new therapeutic areas. We believe this approach may reduce the risks associated with traditional drug development.

TransCon Product Candidate Pipeline



1. Excludes rights granted to VISEN Pharmaceuticals in Greater China
2. In phase 3 development for pediatric growth hormone deficiency in Greater China through VISEN Pharmaceuticals
3. U.S. PDUFA user fee goal date June 25, 2021

We maintain an intellectual property portfolio comprising 198 issued patents and approximately 385 patent applications as of December 31, 2020 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. Other than the rights we have granted to VISEN as noted in this report, 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 global biopharmaceutical company by applying our TransCon technologies to create a pipeline of proprietary products. 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. Our algorithm for product innovation focuses on identifying indications that have an unmet medical need, have a clinically validated parent drug or pathway, are suitable to our TransCon technologies, have a clearly differentiated product, have a potential established development pathway and have a large potentially addressable market.

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. 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. We have disclosed oncology as our second therapeutic area of focus and intend to select a third independent therapeutic area as part of our Vision 3x3 strategic roadmap through 2025.

The key elements of Vision 3x3 include to:

- obtain regulatory approval for three independent 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 establishing global clinical reach either directly or through partnerships, pursuit of 9 total indications, label optimization and lifecycle management activities, and through new endocrinology products;
- establish a global commercial presence for the endocrinology rare disease franchise by building an integrated commercial business in North America and select European countries, and establishing further global presence through partners with local expertise and infrastructure in other geographic areas; and
- create a third independent therapeutic area with a diversified pipeline built on our TransCon technologies and our unique algorithm for product innovation.

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, under three exclusive license agreements, effective November 7, 2018 and as amended January 4, 2021, or the Rights Agreements, 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. In January 2021, we invested additional $12.5 million in VISEN as part of VISEN's $150 million Series B financing. Following the Series B financing, we retained approximately 44% of VISEN's issued and outstanding shares. We believe our investment in 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.

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, antibody 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.

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

Efficacy Benefits

- Same mode of action as parent drug
- Predictable release of unmodified parent drug supporting dosing frequency from daily to up to six months or more
- Designed to enable sustained localized or systemic drug exposure
- Designed to reduce dosing frequency to improve patient adherence and improve overall treatment outcomes
- Dosing and release tailored to desired pharmacokinetic profile and potentially optimizing effects of parent drug

Safety and Tolerability Benefits

- Same predicted safety profile as parent drug with potential enhancements or improvements due to application of TransCon technologies
- May enable comparable alternative to continuous infusions or subcutaneous injections
- TransCon localized delivery platform may offer improved safety profile by maintaining high local concentrations of drug while minimizing systemic exposure
- Immunogenic potential, or the ability of a substance to provoke an immune response, comparable to parent drug

Development Benefits

- Potentially higher drug development success rate when investigating clinically validated parent drugs and mechanisms by leveraging existing knowledge

Intellectual Property Benefits

- 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.

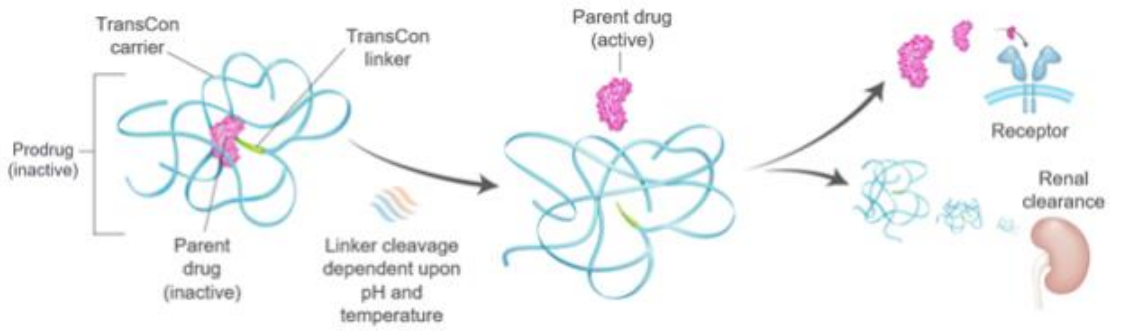
TransCon Linkers

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 potentially 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 always 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.

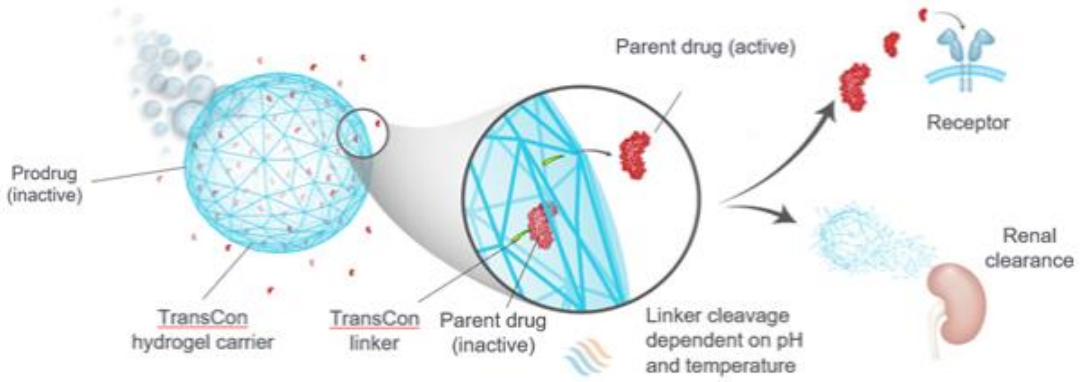
TransCon Carriers

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, lonapegsomatropin, 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 current and future 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 are currently used to create potentially best-in-class 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 biology.

TransCon Product Candidates - Endocrinology

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 somatropin (hGH). Daily therapy with hGH has been shown to increase growth in children, and improve metabolic effects, including reducing adiposity and improving cardiovascular health in both children and adults. These daily hGH therapies have been shown to be safe and well-tolerated.

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

Despite the demonstrated benefits of hGH therapy, adherence 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 adherent with their daily dosing schedule, and therefore fail to achieve expected treatment outcomes. According to a 2018 study (Graham et al), as many as seven out of ten pediatric patients are non-adherent to daily growth hormone therapy, which may result in significant reductions in the degree of growth and suboptimal outcomes.

Reducing injection frequency is associated with better adherence and thus may improve height velocity (HV) for pediatric patients experiencing poor adherence with daily hGH 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:

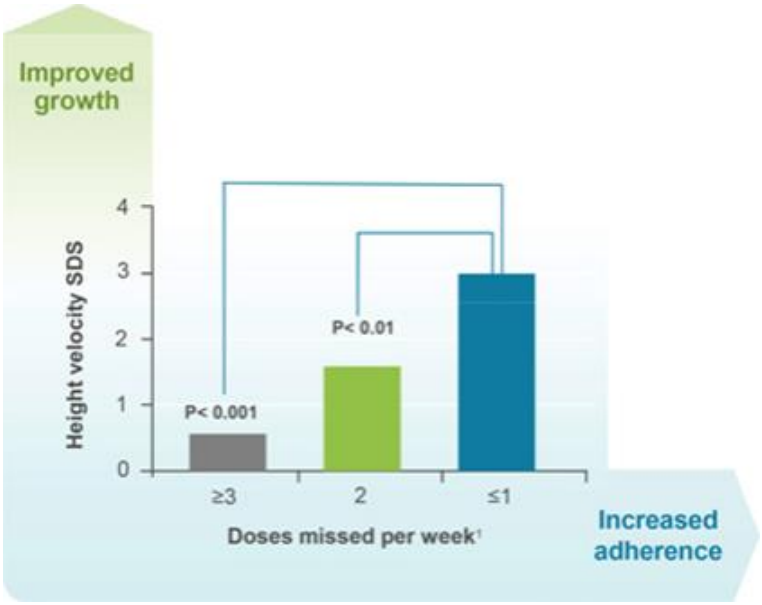


Figure 1. Negative impact of poor compliance on growth response. Patients missing two or more injections per week had a statistically significant reduction in height velocity. (Cutfield et al, 2011.)

Since the introduction of hGH in 1981, a number 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 somatropin (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 most of the 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 hGH products are currently estimated at approximately $4 billion. 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 lonapegsomatropin as a once-weekly somatropin (hGH) 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 Therapies

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

- Unmodified somatropin (hGH): 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, or EMA, in 2013, and later withdrawn. 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.
- Permanent modification of growth hormone: Modification technologies prolong 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 somatropin (hGH) and may also negatively impact the drug's safety.

To our knowledge, as of the date of this report, there are no commercially available long-acting growth hormone treatment options 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.

On August 28, 2020, the FDA granted Novo Nordisk Inc. approval of somapacitan for replacement of endogenous growth hormone in adult patients with GHD but as of the date of this report to our knowledge Novo Nordisk has not commercially launched the product in the United States. In January 2021, Novo Nordisk received a positive opinion from the Committee for Medicinal Products for Human Use, under the EMA for once-weekly somapacitan, recommending marketing authorisation for use in adult patients with GHD. Pfizer (in collaboration with OPKO Health Inc.) has submitted to the FDA, a Biologics License Application, or BLA, for somatrogon, a long-acting growth hormone for the treatment of pediatric patients with GHD. In January 2021, Pfizer (in collaboration with OPKO Health) announced the FDA has accepted the regulatory submission and set the PDUFA goal date in October 2021.

Other experimental growth hormone therapies based on permanent modification are in different stages of clinical development by various companies, including GeneScience Pharmaceuticals Co., Ltd., Genexine Inc., I-MAB, and JCR Pharmaceuticals Co., Ltd.

Our Solution: Lonapegsomatropin

Lonapegsomatropin is an investigational long-acting prodrug of somatropin (hGH) 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, somatropin, as daily hGH therapy. lonapegsomatropin is composed of an unmodified somatropin that is transiently bound to a carrier and proprietary linker.

We believe our once-weekly Lonapegsomatropin has 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 lonapegsomatropin to daily growth hormone in an identical clinical setting.

In October 2019, we received Orphan Designation from the European Commission for lonapegsomatropin for pediatric GHD. Orphan Designation is granted to therapies aimed at the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating, affects no more than five in 10,000 persons in the European Union, or EU, and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would provide significant additional benefit over existing therapies). We received Orphan Drug Designation, or ODD, from the FDA for lonapegsomatropin as a treatment for GHD in April 2020.

Clinical Development of Lonapegsomatropin for Pediatric GHD

Our phase 3 pediatric program for lonapegsomatropin consists of the heiGHt, fliGHt and enliGHten Trials. The two-year follow-up data for the phase 3 program for pediatric GHD provides the safety database to support our BLA submission to the U.S. FDA in June of 2020 and our Marketing Authorisation Application, or MAA, to the EMA in September of 2020.

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 lonapegsomatropin (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, followed by a test of superiority if non-feriority was met. Two subjects, one from each arm, withdrew from the trial prior to the final visit.

Results showed that once-weekly lonapegsomatropin 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 least squared mean (LS Mean) results from an ANCOVA model, lonapegsomatropin 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 lonapegsomatropin was significantly greater than the daily hGH (p=0.0088).

The AHV was greater for lonapegsomatropin than for the daily hGH at each visit, with the treatment difference reaching statistical significance from and including week 26 onward. The incidence of subjects with AHV < 8 cm/year at 52 weeks, referred to as poor responders was 4% and 11% in the lonapegsomatropin 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 lonapegsomatropin 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 analyses from the heiGHt Trial showed:

- No incidence of treatment emergent anti-hGH neutralizing antibodies detected, and post-baseline low level of low-titer non-neutralizing anti-hGH binding antibodies was similar between the two arms (6 [5.7%] in lonapegsomatropin vs. 2 [3.6%] in Genotropin arm).
- Height SDS at 52 weeks increased over baseline by 1.10 for lonapegsomatropin and by 0.96 for the daily hGH, with the treatment difference increasing at each visit over 52 weeks.
- Body Mass Index (BMI) was in the normal range over 52 weeks in both the lonapegsomatropin group (with a mean increase in BMI SDS from -0.32 at baseline to -0.03 at Week 52) and in the daily hGH group (with a mean BMI SDS decrease from -0.14 at baseline to -0.40 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.
- Model-derived mean average insulin-like growth factor-1 (IGF-1) SDS values were 0.72 for lonapegsomatropin and -0.02 for the daily hGH at week 52.
- Adverse events leading to dose reduction (IGF-1 levels or clinical symptoms) occurred twice in the lonapegsomatropin arm (representing 1.9 percent) and once in the daily hGH arm (representing 1.8 percent).

- Observed change in bone age over 52 weeks from baseline was 1.36 years for the lonapegsomatropin arm and 1.35 years in the daily arm.

Additional Clinical Trials of TransCon hGH in Pediatric Subjects with GHD

The results presented for the heiGHt Trial are consistent with findings from the phase 2 trial, an active-controlled trial which found that three different doses of TransCon hGH were comparable to daily hGH in 53 treatment-naïve, pre-pubertal children with GHD. The phase 2 trial was conducted with a bioequivalent predecessor molecule and 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.

The single arm phase 3 fliGHt Trial of lonapegsomatropin was designed to create additional exposures and expand the safety database for lonapegsomatropin in pediatric subjects. In this single arm open-label trial, 146 patients were enrolled, and subjects switched from daily hGH to weekly lonapegsomatropin with a primary objective of evaluating the safety and tolerability of lonapegsomatropin in subjects with pediatric GHD. Results of the trial indicated treatment with lonapegsomatropin was safe and well-tolerated in those with pediatric GHD who were previously treated with commercially-available daily growth hormone therapies. The safety profile of lonapegsomatropin was similar to the published safety profile of daily growth hormone therapies. We believe the results from the fliGHt Trial support switching to once-weekly lonapegsomatropin from a daily hGH, and also provide evidence supporting the tolerability of lonapegsomatropin in subjects under three years of age.

Nearly all subjects who completed the heiGHt or fliGHt Trials have enrolled in the open-label extension study, the enliGHten Trial, which is designed to provide long-term safety data to support the regulatory filings for lonapegsomatropin. We initiated the enliGHten Trial in 2017, and approximately 300 pediatric subjects enrolled. Data from enliGHten formed the long-term safety database supporting our BLA submission to the FDA for lonapegsomatropin for the treatment of pediatric GHD which occurred in June 2020, as well as submission of a MAA to the EMA which occurred in September 2020. The PDUFA user fee goal date is set for June 25, 2021. If approved by the FDA, we expect to commercially launch lonapegsomatropin for the treatment of pediatric GHD in the U.S. in the third quarter of 2021. In addition, in July 2020, we received approval of our proposed Paediatric Investigation Plan covering ages 6 months to less than 18 years of age from the EMA for lonapegsomatropin and we anticipate the European Commission to issue a decision on our MAA in the fourth quarter of 2021.

Additionally, in January 2021, we announced 104-week analysis of data from the ongoing enliGHten Trial, including follow-up on subjects from heiGHt who continued into enliGHten. The data showed maintenance of a treatment advantage in subjects initially treated with lonapegsomatropin beyond the first year of therapy. The safety results, which were comparable to Genotropin in the phase 3 heiGHt Trial, were consistent across the phase 3 clinical trials.

In September 2020, we filed a Clinical Trial Notification with the Pharmaceuticals and Medical Device Agency in Japan to initiate the company’s phase 3 riGHt Trial of lonapegsomatropin for the treatment for pediatric GHD. The primary objective of the riGHt Trial is to evaluate and compare the annualized height velocity of 40 Japanese prepubertal treatment naïve children with GHD treated with weekly lonapegsomatropin to that of a commercially available daily hGH formulation at 52 weeks.

VISEN, our strategic investment partner, is conducting a clinical study in China evaluating lonapegsomatropin for the treatment of pediatric GHD.

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 lonapegsomatropin. In May 2019, we introduced the auto-injector into the enliGHten Trial and we expect to make it available to patients in conjunction with a potential commercial launch. Over 160 subjects have used auto-injector and dual-chamber cartridges in the enliGHten extension trial, which we believe meets our objective of collecting required usability data to support inclusion of the auto-injector as part of our initial BLA submission.

The auto-injector provides for room temperature storage, includes an empty-all design and is expected to last for at least four years. With simple operation, the 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. 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 adherence over time.

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

Clinical Development of Lonapegsomatropin in Adults

We have successfully completed 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. We have also completed several phase 1 trials in healthy adult subjects.

Following our phase 2 study and discussions with the FDA, we submitted an amendment to our IND to initiate the foresiGHt Trial, a global phase 3 study with the aim to demonstrate the metabolic benefits of lonapegsomatropin in adults, with the primary objective to evaluate change in trunk fat percentage. The three arms of the study include patients treated with once-weekly lonapegsomatropin, once-weekly placebo, and daily hGH with patients randomized in a 1:1:1 ratio. The primary endpoint of the study is a change from baseline in percentage trunk fat at 38 weeks. Following the 38-week main period, all patients will receive once-weekly lonapegsomatropin during the 52-week open-label extension. We expect to complete enrollment of foresiGHt by the end of 2021 or early 2022.

Future Development Plans

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

TransCon PTH

Market Opportunity in Hypoparathyroidism

Hypoparathyroidism, or HP, is a rare endocrine disease characterized by deficient or absent parathyroid hormone, or PTH, affecting approximately 200,000 patients in the U.S., Europe, Japan and South Korea. 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. Short term symptoms include weakness, severe muscle cramps (tetany), abnormal sensations such as tingling, burning and numbness (paresthesia), memory loss, impaired judgement and headache. Over the long term, treatment with the current standard of care, or SoC, can increase risk of major complications, such as extraskeletal calcium depositions occurring within the brain, lens of the eye, and kidneys, which can lead to impaired renal function. Patients often experience decreased quality of life.

PTH controls serum calcium via several mechanisms. PTH acts to release calcium from the skeleton by regulating bone turnover, 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.

Current SoC for HP patients primarily consists of active vitamin D and oral calcium 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 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. SoC with active vitamin D and calcium have been shown to contribute to the risk of renal disease.

HP also poses a high burden on the healthcare system despite current SoC. For example, one survey of 374 patients showed that 72% experienced more than ten symptoms in the preceding twelve months, with symptoms experienced for a mean of 13 ± 9 hours a day. Other studies showed that 79% of HP cases require hospitalizations and that patients with the disease results have a four-fold increase in the risk of renal disease compared to healthy controls. Patients often experience decreased quality of life. We conducted a survey of 42 patients which found that 100 percent of subjects reported negative psychological impacts, interference with daily life and impact on physical functioning from HP, and that 76 percent were either no longer able to work or experienced interference with work productivity.

An effective PTH replacement therapy that fully addresses the condition is not widely available to patients with HP in the U.S. 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 was voluntarily recalled in September 2019 in the U.S. and is now only available to a limited number of patients through a Special Use Program offered by its manufacturer, Takeda Pharmaceutical Company. We are also aware of several academic groups and companies working on making longer-acting agonists of the PTH receptor, or PTH1R. In addition, other companies and groups are developing or commercializing therapies for hypoparathyroidism, including Shire, Chugai Pharmaceutical Co., Ltd., Entera Bio, Extend Biosciences, Massachusetts General Hospital, Amolyt Pharma, Prolynx Inc., and Eli Lilly and Company.

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 an investigational long-acting prodrug of parathyroid hormone, or PTH, that is designed as a novel replacement therapy for 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.

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 thereby maintaining blood calcium levels and normalizing urinary calcium excretion. Pharmacokinetic data from multiple ascending dose (MAD) cohorts in our phase 1 trial of TransCon PTH in healthy subjects demonstrated an infusion-like profile of free PTH. By providing steady levels of PTH in the physiological range, we believe TransCon PTH can address the fundamental limitations of short-acting PTH molecules and become a highly differentiated therapy for HP.

Clinical Development of TransCon PTH for Adult Hypoparathyroidism

Our ongoing phase 2 PaTH Forward Trial is evaluating the safety, tolerability and efficacy of three fixed doses (15, 18, or 21 µg per day) of TransCon PTH compared to placebo over a four-week double-blinded period, followed by a range of doses intended to cover the range of individual requirements for hormone replacements in a long-term open-label extension, or OLE, using a ready-to-use prefilled pen device. The goal of PaTH Forward is to evaluate TransCon PTH control of serum and urinary calcium, identify a starting dose for a pivotal phase 3 trial, and establish a titration regimen for complete withdrawal of SoC.

Previously, in May 2018, we completed a phase 1 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 ten 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 calcium; and, incidence of anti-PTH and anti-PEG antibodies.

Results of the trial showed that 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 ten repeated doses, free PTH exhibited a flat, infusion-like profile. TransCon PTH was also observed to have the expected effects on renal calcium reabsorption as evaluated by on fractional excretion of calcium, and also down regulation of endogenous PTH(1-84) secretion.

In April 2020, we announced top-line data from the four-week fixed dose, double-blinded portion of PaTH Forward, a global phase 2 study evaluating the safety, tolerability and efficacy of TransCon PTH in adult subjects with hypoparathyroidism. A total of 59 subjects were randomized in a blinded manner to receive fixed doses of TransCon PTH at 15, 18 or 21 µg/day or placebo for four weeks using a ready-to-use prefilled pen injector planned for commercial presentation. All doses of TransCon PTH were well-tolerated, and no serious or severe treatment-related adverse events, or TEAEs, were observed at any point. No treatment-emergent adverse events led to discontinuation of study drug, and the overall incidence of TEAEs was comparable between TransCon PTH and placebo. Additionally, there were no drop-outs during the four-week fixed dose period. In the modified full analysis set (n=57), TransCon PTH eliminated standard of care (i.e. off active vitamin D and £ 500 mg per day of calcium supplements) in 100 percent of subjects in the highest dose arm (21 µg/day) and 82 percent of subjects across all dosage arms. Fifty-eight subjects reached the six-month analysis in the OLE portion of the trial, where they receive a customized maintenance dose of TransCon PTH (6 to 30 µg per day).

Preliminary six-month results from the PaTH Forward OLE demonstrated

- 91 percent of all subjects eliminated standard of care (defined as (1) off active vitamin D and (2) £500 mg per day of calcium supplements), including 76 percent who eliminated all supplements.
- 86 percent of all subjects normalized or reduced by 50 percent 24-hour urine calcium.
- All mean summary and subdomain SF-36® Health Survey scores normalized despite all mean scores starting below norms at baseline including subjects randomized to placebo who switched to TransCon PTH group at week four. Importantly, subjects randomized to TransCon PTH demonstrated continued improvements from week four to month six.
- Bone mineral density mean Z-scores trended towards normalization at week 26.
- All doses of TransCon PTH were well-tolerated, and no treatment-related serious or severe adverse events were observed at any point. No subjects had PTH treatment-emergent adverse events related to hyper- or hypocalcemia leading to emergency visit, urgent care visit, or hospitalization.
- Adherence to daily injections of TransCon PTH was 99.8 percent.

As of March 10, 2021, fifty-eight out of the fifty-nine patients continued in the open-label extension portion of the trial, where they receive a customized maintenance dose of TransCon PTH (6 to 30 µg per day).

In September 2020, we submitted an amendment to our IND to initiate PaTHway, our global phase 3 clinical trial evaluating the safety, tolerability and efficacy of TransCon PTH in adults with HP following discussions with FDA and European regulatory authorities. The double-blind, placebo-controlled trial is expected to enroll approximately 76 subjects at sites in North America and Europe in order to obtain 68 evaluable subjects. We expect topline results from this trial in the fourth quarter of 2021. In addition, we are planning to conduct a phase 3 study in Japan designed to evaluate the safety, tolerability, and efficacy of TransCon PTH. We anticipate filing a Clinical Trial Notification for this proposed phase 3 study in the second quarter of 2021.

In June 2018, we were granted ODD by the FDA, for TransCon PTH for the treatment of for hypoparathyroidism. In October 2020, we were granted Orphan Designation by the European Commission for TransCon PTH for the treatment of hypoparathyroidism.

TransCon CNP

Market Opportunity in Achondroplasia

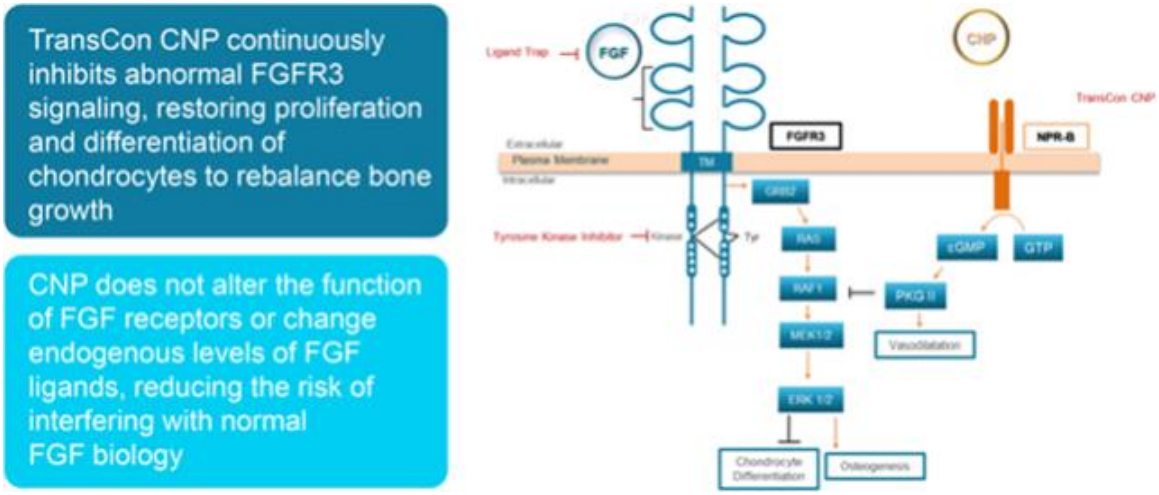
Achondroplasia is the most common form of dwarfism, occurring in about one in 10,000 to 30,000 newborns or approximately 250,000 worldwide. Achondroplasia results in severe skeletal complications and comorbidities, including spinal stenosis due to premature fusion of the foramen magnum, sleep apnea, 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 a CNP analog to children with achondroplasia and in animal models of achondroplasia has been found to stimulate growth.

BioMarin Pharmaceutical, Inc. is developing vosoritide for the treatment of achondroplasia, and other companies that are developing therapies for achondroplasia include Pfizer, QED Therapeutics and BioClin Therapeutics, Inc.



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

Figure 3. The role of a defect in the FGFR3 signaling pathway in the development of achondroplasia is well understood.

Our Solution: TransCon CNP

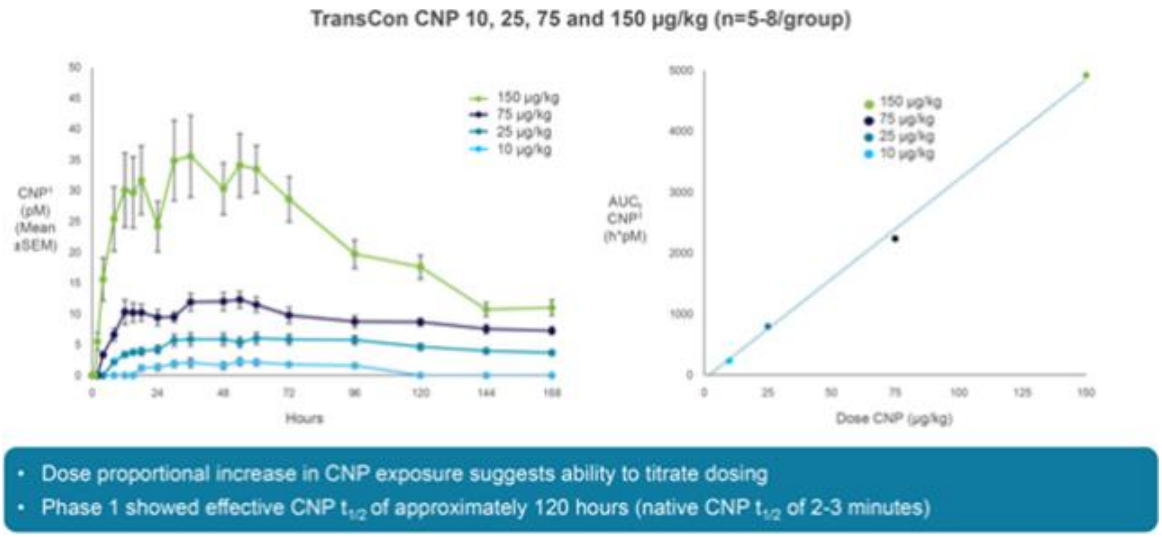
TransCon CNP is an investigational long-acting prodrug of C-type natriuretic peptide designed to provide continuous CNP exposure at therapeutic levels with a well-tolerated and convenient once-weekly dose. It is being developed for the treatment of children with achondroplasia. TransCon CNP is designed 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, reduce binding of CNP to the NPR-B receptor in the cardiovascular system to avoid hypotension, and release unmodified CNP, which is small enough in size to allow effective penetration into growth plates. We believe TransCon CNP offers advantages over short-acting CNP and CNP analogs in development that result in high Cmax levels which may cause adverse cardiovascular events. In addition, we expect a more constant CNP exposure at lower Cmax to correlate with better therapeutic outcomes.

Clinical Development of TransCon CNP for Achondroplasia

TransCon CNP is currently being evaluated in a global phase 2 trial, known as the ACcomplisH Trial, which is designed to evaluate the safety and efficacy of TransCon CNP in children (ages two to ten years) with achondroplasia.

Results from our phase 1 trial of TransCon CNP in healthy adult subjects 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 µg/kilogram. Up to ten 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 µg/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. No anti-CNP antibodies were detected in any subjects.



1 CNP measured as CNP-38.

Figure 4. Pharmacokinetic results for TransCon CNP 10, 25, 75 and 150 µg/kg administered as a once-weekly subcutaneous injection are presented.

Following completion of the phase 1 trial, and a successful submission of an IND in July 2019, we initiated the phase 2 ACcomplisH Trial, a randomized, double-blind, placebo-controlled, sequential rising dose trial to evaluate the safety and efficacy of TransCon CNP in approximately 60 children with achondroplasia (ages two to ten years). Subjects will be randomized to receive either TransCon CNP or placebo in a 3:1 ratio. The primary efficacy endpoint is annualized height velocity at twelve months. Key secondary and additional endpoints include body proportionality and change in BMI, both evaluated after twelve months of weekly TransCon CNP treatment, and patient reported outcome (PRO) measures. We continue to work towards escalating sequential dose cohorts throughout this year.

In collaboration with VISEN, we are sponsoring the ACcomplisH China Trial, a randomized, double-blind, placebo-controlled, phase 2 dose expansion trial to evaluate the safety and efficacy of TransCon CNP in subjects with achondroplasia. The primary endpoint is to evaluate the safety of treatment and its effect on 12-month annualized height velocity. In January 2021, China Center for Drug Evaluation (CDE) of National Medical Products Administration (NMPA) approved VISEN's IND application to conduct the ACcomplish China Trial.

In parallel, we are conducting the ACHieve Study, a multi-center natural history study designed to gain insight into the experience of pediatric subjects with achondroplasia. ACHieve will study growth velocity, body proportionality, and comorbidities over time of children with achondroplasia up to eight years old. No study medication will be administered.

We plan to provide a TransCon CNP clinical program update in the fourth quarter of 2021.

In February 2019, we were granted ODD by the FDA for TransCon CNP for the treatment of achondroplasia. In August 2020, we received Orphan Designation from the European Commission for TransCon CNP for the of achondroplasia.

TransCon Product Candidates - 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 $124 billion in 2018 with projected growth to $237 billion in 2024.

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 parental 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

Building from the success of our programs in endocrinology, our vision in oncology is to create best-in-class therapeutics by applying both systemic and sustained localized TransCon technologies for clinically validated pathways. By applying our unique algorithm for product innovation, we believe we can improve outcomes in oncology currently limited by suboptimal efficacy and systemic toxicity.

We believe TransCon is particularly well-suited to oncology because of the large number of validated targets with known limitations. We are working to not only prolong the activity of approved drugs at efficacious levels, but to extend the exposure times without reaching high toxic levels that often complicate oncology therapeutic regimens. By prolonging therapeutic levels, we believe that our technologies have the potential to increase the efficacy of small molecules, peptides and proteins without increasing toxicity – addressing a long-standing challenge in oncology.

Our TransCon product candidates in oncology are designed for sustained systemic or intratumoral administration to provide durable and potent anti-tumor effects. TransCon product candidates can be designed to facilitate all the critical steps of the cancer immunity cycle that lead to eradication of malignant cells. We believe these product candidates have the potential 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 both tolerability and efficacy, as high local drug concentration may be achieved, while maintaining low systemic exposure. In addition, TransCon product candidates are designed for sustained release and, hence, may allow for reduced frequency of dosing, enabling treatment of tumor types that cannot be easily accessed for frequent injection.

We have conducted nonclinical studies that have found that our oncology product candidates can slowly release immuno-oncology agents, highlighting their potential to enhance the immune system to attack malignant tumor cells.

Development of TransCon Product Candidates in Oncology

Our goal is to improve treatment efficacy while limiting or reducing toxicity by applying TransCon technologies to clinically validated pathways, using our unique algorithm for product innovation. We are conducting nonclinical 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 currently advancing two product candidates:

- TransCon TLR7/8 Agonist is designed for sustained release of TLR7/8 agonist, resiquimod, and intended for intratumoral administration. This product candidate is designed to provide potent activation of the innate immune system in the tumor and draining lymph nodes and to have low risk of systemic toxicity. In December 2020, we filed an IND with the U.S. Food and Drug Administration to initiate the clinical program of TransCon TLR7/8 Agonist with the transcendIT-101 Trial. We expect initial results from the first part of transcendIT-101, monotherapy dose escalation, in the fourth quarter of 2021. We plan to initiate the second part of transcendIT-101, dose escalation of TransCon TLR7/8 Agonist in combination with a checkpoint inhibitor, in the second quarter of 2021.
- TransCon IL-2 b/g is designed for prolonged exposure of an IL-2 variant that selectively activates the IL-2Rb/g with minimal binding to IL-2Rα. This product candidate is designed to provide potent anti-tumor activity and to have reduced risk of toxicity, such as vascular leak syndrome. We plan to submit an IND or similar for TransCon IL-2 b/g in the third quarter of 2021.

We are evaluating additional TransCon product candidates in nonclinical 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.

We believe these programs have potential to target multiple steps of the immunity cycle that drives the immune response against tumor cells.

Strategic Collaborations

We also engage in strategic collaborations to further leverage our TransCon technologies in certain geographies with market-leading biopharmaceutical companies. These collaborations aim to further monetize both our TransCon technologies and our internal 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.

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. In January 2021, we invested additional $12.5 million in VISEN as part of VISEN's $150 million Series B financing. Following the Series B financing, we retain approximately 44% of VISEN's issued and outstanding shares. In October 2019, VISEN received approval of a clinical trial application for TransCon hGH from the Center for Drug Evaluation in China and initiated a phase 3 trial in pediatric growth hormone deficiency. In January 2021, China's CDE approved VISEN's application to conduct the ACcomplish China Trial, a randomized, double-blind, placebo-controlled, phase 2 dose expansion trial to evaluate the safety and efficacy of TransCon CNP in subjects with ACH.

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.

Amended and Restated Shareholders Agreement

In connection with the Company's investment in VISEN, on January 8, 2021, the Company entered into an Amended and Restated Shareholders Agreement (the "Amended Shareholders Agreement"), amending and restating the Shareholders Agreement dated November 7, 2018, between the Company and the parties set forth therein (the "Shareholders Agreement"). In addition to rights previously granted under the Shareholders Agreement, under the Amended Shareholders Agreement, the Company has the right to designate two individuals for election to the board of directors of VISEN, which individuals are initially Jan Møller Mikkelsen and Michael Wolff Jensen. In addition, VISEN has agreed that certain specified events (including certain liquidation events) shall require the approval of (i) shareholders of VISEN holding at least 50% of VISEN's Series B preferred shares, (ii) shareholders of VISEN holding at least 60% of VISEN's Series A preferred shares and/or (iii) certain members of VISEN's board of directors. The Amended Shareholders Agreement can be terminated by written agreement among the holders of at least 60% of VISEN's Series A preferred shares and at least 50% of VISEN's Series B preferred shares.

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 and are subject to long term forecasting obligations and certain minimum purchase requirements for all parts of the commercial supply chain.

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, 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 (v) 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 diseases 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 six 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.

Lonza Tech Transfer and Manufacturing Agreement

On December 12, 2019, we entered into a multi-year commercial supply agreement (the "Lonza Agreement") with Lonza Ltd ("Lonza"). Under the Lonza Agreement, Lonza has agreed to manufacture and supply drug substance for our TransCon hGH product candidate (the "TransCon hGH Drug Substance"). We may purchase TransCon hGH Drug Substance from other manufacturers but have granted Lonza status as primary supplier of TransCon hGH Drug Substance and are obligated to purchase a certain minimum annual quantity of TransCon hGH Drug Substance per year starting in 2023.

The Lonza Agreement secures us a certain capacity of TransCon hGH Drug Substance per year. For requirements above such capacity, we are free to have manufactured and purchase TransCon hGH Drug Substance from other suppliers, including but not limited to, subject to certain restrictions, transferring the manufacturing process of TransCon hGH Drug Substance to ourselves.

The Lonza Agreement is effective as of December 12, 2019. The initial term of the Lonza Agreement expires seven years after first approval of a drug product manufactured using the TransCon hGH Drug Substance (the "Lonza Initial Term") unless earlier terminated. During the first five years of the Lonza Initial Term, we may decide, in our sole discretion, to extend the term of the Lonza Agreement by two years. The Lonza 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 either party for a continuing event of force majeure, (iv) by either party upon written notice after a specified time period in the event of our change of control, and (v) by either party in the event of the occurrence of certain conditions related to the manufacturing of the TransCon hGH Drug Substance as more fully described in the Lonza Agreement.

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

Sharp Corporation Packaging and Supply Agreement

On December 1, 2019 we entered into a multi-year packaging agreement (the "Sharp Agreement") with Sharp Corporation ("Sharp"). Under the Sharp Agreement, Sharp will package, assemble, and label TransCon hGH for commercial use in certain territories, including the United States and the European Union. We are non-exclusive to Sharp and may engage other manufacturers to package, assemble, and label TransCon hGH but we are obligated to meet certain minimum spend requirements for TransCon hGH during the first 12-month period after first shipment of TransCon hGH for commercial sale after regulatory approval thereof.

The Sharp Agreement is effective as of December 1, 2019. The initial term of the Sharp Agreement expires on December 31, 2025 and will be automatically extended for additional two-year periods unless earlier terminated. The Sharp Agreement may be terminated (i) by either party upon mutual consent, (ii) by either party for the other party's uncured material breach, (iii) by either party for the other party's bankruptcy or insolvency-related events, (iv) by either party for a continuing event of force majeure, (v) by either party after the initial term of the Sharp Agreement has been completed.

The Sharp Agreement contains, among other provisions, certain warranties by Sharp, 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.

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."

As of December 31, 2020, we own a total of 87 patent families, of which 29 are currently in their priority year or international phase and we own several granted patents in the United States (28), Europe (17), Australia (26), Canada (19), China (7), Israel (13), Indonesia (2), India (4), Korea (3), Malaysia (5), New Zealand (4), Japan (17), Mexico (13), Singapore (7), Russia (10), the United Arab Emirates (1) and South Africa (21) and have approximately 389 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, 2020 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 seven 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, 2020, this patent family included patents granted in Europe and the United States. 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, 2020, this patent family included patents granted in the United States, Europe, Australia, Brazil, 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, 2020, 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, 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, 2020, this patent family included patents granted in the United States, Europe, Australia, Canada, India, Israel, Mexico, Singapore and South Africa and included patent applications in the United States and Brazil. 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, 2020, this patent family included patents granted in the United States, Japan, Russia and 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, 2020, 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.

The seventh of these patent families is directed to potential superior efficacy achieved with TransCon hGH treatment. This patent family is currently in PCT phase and any patents granted thereof are expected to expire in March 2040.

Seven of the nine patent families covering the auto-injector device with a filing date of December 29, 2016, include patent applications in the United States, Europe, Australia, Canada, Japan and New Zealand and one granted patent in the United States as of December 31, 2020. We expect any patents granted from these patent families to expire in December 2036. As of December 31, 2020 the other two patent families covering the auto-injector device with a filing date of May 23, 2018 and June 29, 2018, respectively, include patent applications in the United States, Europe, the United Arab Emirates, Australia, Brazil, Canada, China, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore and South Africa and one granted patent in South Africa. We expect any patents granted from these patent families to expire in March and June 2038, respectively.

TransCon PTH

Our patent portfolio related to TransCon PTH includes nine 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, 2020, this patent family included granted patents in the United States, Europe, the United Arab Emirates, Australia, Canada, China, Israel, Japan, Mexico, Russia and South Africa and included patent applications in Europe, the United States, 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, 2020, 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 and Thailand and a granted patent in 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, 2020, one of these patent families includes patent applications in the United States, Europe, Australia, Brazil, Canada, China, Israel, Indonesia, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore and Thailand and a granted patent in South Africa. The other one of these patent families includes patent applications in the United States, Europe, Australia, Canada, China and Japan. 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, 2020, this patent family includes patent applications in the United States, Europe, Australia, Brazil, Canada, China, Israel, Japan, South Korea, Mexico, New Zealand, Russia and Singapore and a granted patent in South Africa. 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, 2020, this patent family includes patent applications in the United States, Europe, Australia, Brazil, Canada, China, Indonesia, Israel, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore, Thailand and South Africa. We expect any patents granted from this patent family to expire in May 2039.

The seventh patent family relates to a pharmaceutical composition comprising reversible PTH conjugates. As of December 31, 2020, this patent family consists of an international application. We expect any patents granted from this patent family to expire in February 2040.

The eighth and ninth patent families relate to a method of titrating hypoparathyroidism patients off of standard of care within four weeks from the beginning of daily treatment with a PTH compound and the treatment of the physical and mental well-being of hypoparathyroidism patients, respectively. As of December 31, 2020, these patent families are in their priority year. We expect any patents granted from these patent families to expire in January 2041 and September 2041, respectively.

TransCon CNP

Our patent portfolio related to TransCon CNP includes eleven 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, 2020, 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, 2020, this patent family included granted patents in the United States, Europe, the United Arab Emirates, Australia, Brazil, Canada, China, Israel, Japan, Mexico and South Africa and included patent applications in Europe, the United States, 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, 2020, 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 and Thailand and a granted patent in Russia, Singapore and South Africa. We expect any patents granted in this patent family to expire in January 2036.

The fourth to the ninth patent families are composition of matter patent families directed various CNP compounds having beneficial properties. As of December 31, 2020, the first one of these six patent families included patent applications in the United States, Europe, Australia, Canada, Japan, Mexico and New Zealand and a granted patent in the United States and South Africa. As of December 31, 2020, the second one included patent applications in the United States, Europe, Australia, Canada, Japan and New Zealand and a granted patent in South Africa. As of December 31, 2020, 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 and Singapore and a granted patent in South Africa. As of December 31, 2020, the fourth one included patent applications in the United States, Europe, Australia, Canada, Israel and New Zealand. As of December 31, 2020, 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, 2020, the sixth one included patent applications in the United States, Europe, Australia, Canada, Israel and New Zealand. We expect any patents granted in these patent families to expire in January 2037.

The tenth patent family covers a combination therapy of TransCon CNP. As of December 31, 2020, this patent family includes patent applications in the United States, Europe, Australia, Brazil, Canada, China, Indonesia, Israel, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore and Thailand and a granted patent in South Africa. We expect any patents granted from this patent family to expire in September 2037.

The eleventh patent family relates to a pharmaceutical composition comprising reversible CNP conjugates. As of December 31, 2020, this patent family consists of an international application. We expect any patents granted from this patent family to expire in February 2040.

General Field of Oncology

As of December 31, 2020, our oncology-related patent portfolio includes thirteen patent families relating to various TransCon oncology product candidates, of which, except for one, all are currently in their priority year or in international phase. We expect any patents granted in these patent families to expire in or after March 2039.

TransCon TLR7/8

As of December 31, 2020, our patent portfolio related to TransCon TLR7/8 includes six patent families. The first patent family relates to hydrogels, which are first synthesized and subsequently loaded with drug-linker conjugates. As of December 31, 2020, this patent family included granted patents in the United States and in Europe and a patent application in Europe. We expect any patents granted in these patent families to expire in July 2025.

The second patent family relates to a specific class of PEG-based hydrogels. As of December 31, 2020, this patent family included granted patents in Europe, Australia, Brazil, Canada, China, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore and South Africa and patent applications in the United States, Europe and Thailand. We expect any patents granted in this patent family to expire in July 2030.

The third patent family relates to a broad class of TransCon TLR7/8 candidate structures. As of December 31, 2020, this patent family consist of an international application and patent applications in Argentina and Taiwan. The fourth to sixth patent families relate to TransCon TLR7/8 compounds having beneficial properties. As of December 31, 2020, these patent families consist of one international application each. We expect any patents granted in all four of these patent families to expire in January 2040.

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 15 patent families relating to TransCon linkers, the material components of which are described above. We own an aggregate of 11 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, 2020, this patent family included patents 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.

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 on clinical studies, issuance of warning letters or other notices of violation, 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 after completion of all pivotal clinical trials;
- 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 of selected clinical investigation sites to assess compliance with GCP; and
- FDA review and approval of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

Nonclinical Studies and Investigational New Drug Applications

Nonclinical studies include laboratory evaluations of product chemistry, toxicity and formulations, as well as animal studies to assess safety and efficacy. An IND is a request for authorization from the FDA to administer an investigational pharmaceutical product to humans. A sponsor must submit the results of the nonclinical tests, together with chemistry, manufacturing & control information, and any available clinical data or literature, to the FDA as part of an IND. Some nonclinical testing may continue 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 sponsor 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 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. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. 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. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients 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 drug has been associated with unexpected serious harm to patients. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health (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, optimal dosage, 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 diseases and to determine optimal dosage.
- phase 3: The product candidate is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, typically in well-controlled 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.

In some cases, the FDA may require, or sponsors may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies, may be conducted after initial marketing approval, and may be used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

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. In addition, written safety reports regarding 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 must be submitted to the FDA.

During the development of a new product candidate, 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 FDA to provide advice, and for the sponsor and the FDA to reach consensus 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 product candidate.

Marketing Approval in the U.S.

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 ten 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 twelve months from the date the NDA or BLA is submitted to the FDA because the FDA has sixty days from receipt to decide whether an application is accepted for filing, as described below.

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 (which are analogous to the NDA safety and effectiveness requirements) 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 as well as consumer representatives, 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.

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 (without prejudice to a subsequent submission). 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.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA or BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may also require one or more Phase 4 post-marketing studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and BLAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Regulation of Combination Products in the United States

Certain products are comprised of components, such as drug components and device components, that would normally be subject to different regulatory frameworks by the FDA and frequently regulated by different centers at the FDA. These products are known as combination products. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established the Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute. A combination product with a primary mode of action attributable to the drug component generally would be reviewed and approved pursuant to the drug approval processes set forth in the FDCA or PHSA. In reviewing the NDA or BLA for such a product, however, FDA reviewers would consult with their counterparts in the FDA's Center for Devices and Radiological Health to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System Regulation applicable to medical devices.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the Fast Track program is intended to expedite or facilitate the process for reviewing new products that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA or BLA is submitted, the product candidate may be eligible for priority review. A Fast Track product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a product candidate with a Fast Track designation and/or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product candidate is eligible for priority review if it is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. For new-molecular-entity NDAs or original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date.

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, Breakthrough Therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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, many types of changes to the approved product, such as adding new indications, manufacturing changes or other labeling claims are subject to prior FDA review and approval.

There also are continuing, annual program fee requirements for certain approved prescription drug or biologic 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 in accordance with the statute and regulations 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. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgement, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances.

The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological 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 or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different product for the same disease or condition or the same product for a different disease or condition.

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. In addition, 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 the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

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, relatively 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.

Drug Product Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

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 does not need to show the product to be effective in the pediatric population studied; rather, if the FDA has requested the study and 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 for purposes of the FDA approval process. This is not a patent term extension, but it effectively extends existing periods of regulatory exclusivity.

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 in the European Union

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 authorized in the EEA before May 20, 2004, 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. Within 15 days of the adoption, the EMA will forward its opinion to the European Commission to start the decision-making phase. Within 15 days a draft implementing decision is sent by the Commission to the Standing Committee on Medicinal Products for Human Use, allowing for its scrutiny by EU countries. These have fifteen days to return their linguistic comments, and 22 days for substantial ones. Once a favorable opinion is reached, the draft decision is adopted via an empowerment procedure. The adoption of the decision should take place within 67 days of the opinion of the EMA. 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 in the European Union

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 ten years have elapsed from the initial authorization of the reference product in the European Union. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten 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 EU 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 EU orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following medicinal product approval. During this ten-year orphan market exclusivity period, no marketing authorization application shall be accepted and no marketing authorization shall be granted for a similar medicinal product for the same indication. 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. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

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 ten-year period of market exclusivity is extended to twelve 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, and transparency laws regarding drug pricing and payments or other items of value provided to physicians and other healthcare providers.

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 strict 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 in light of the prohibitions in the statute. 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. In addition, 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 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. Moreover, 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. 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. 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. As with the 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.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA imposed, among other things, new annual reporting requirements for covered manufacturers for certain payments and "transfers of value" provided to physicians, certain other healthcare professionals beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Covered manufacturers must submit reports by the 90th day of each subsequent calendar year.

The majority of states also have anti-kickback and other fraud and abuse laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers. Certain states also require implementation of 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.

Violation of any of such laws or any other governmental regulations that apply to drug manufacturers may result in significant 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 imprisonment.

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.

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 that they 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. Many countries outside the U.S., including the European Union ("EU") member states, established complex and lengthy procedures to obtain price approvals, coverage and reimbursement. These procedures vary from country to country but are commonly initiated after grant of the related marketing authorization. Many EU member states review periodically their decisions concerning the pricing and reimbursement of medicinal products. The outcome of these reviews cannot be predicted and could have adverse effects on the pricing and reimbursement of our medicinal products in the EU member states.

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 2010, the ACA and related legislation were enacted, which, among other things, (i) increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, (ii) 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, (iii) extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans, (iv) imposed mandatory discounts for certain Medicare Part D beneficiaries, and (v) subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act, enacted on December 22, 2017, removes penalties for not complying with the ACA'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 because the individual mandate is a critical and inseverable feature of the ACA, the remaining provisions of the ACA were invalid as well. Upon appeal, the U.S. Court of Appeals for the Fifth Circuit affirmed that the individual mandate was unconstitutional but remanded the case back to the U.S. District Court to determine what portions of the ACA, if any, might continue to be valid. On January 21, 2020, the U.S. Supreme Court declined a motion by the U.S. House of Representatives and others seeking expedited review of the case. It is unclear how these decisions, subsequent appeals and other efforts to challenge, repeal or replace the ACA will impact the law.

On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. These measures include reductions in Medicare payments to providers, capped at 2% per fiscal year, which went into effect on April 1, 2013. These reductions, extended by subsequent legislation, will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced certain Medicare payments to several types of providers, including hospitals. The legislation also 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 through constraints on reimbursement, imposition of mandatory discounts, restrictions on access to certain products, transparency measures, and programs for importation from other countries or 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 EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems, parallel distribution and parallel trade. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced countries. Reductions in the pricing of our medicinal products in one EU member state could affect the price in other EU member states and, thus, have a negative impact on our financial results.

Health Technology Assessment, or HTA, of medicinal products in the EU is an essential element of the pricing and reimbursement decision-making process in a number of EU member states. The outcome of HTA has a direct impact on the pricing and reimbursement status granted to the medicinal product. A negative HTA by a leading and recognized HTA body concerning a medicinal product could undermine the prospects to obtain reimbursement for such product not only in the EU member state in which the negative assessment was issued, but also in other EU member states.

In 2011, Directive 2011/24/EU was adopted at the EU level. This Directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on January 31, 2018, the European Commission adopted a proposal for a regulation on HTA. The European Commission has stated that the role of the draft HTA regulation is not to influence pricing and reimbursement decisions in the individual EU member states. However, this consequence cannot be excluded.

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.

Data Privacy and Security

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 or may become subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA, and, in the EEA, the GDPR. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

In the U.S., HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. In addition, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, effective January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context. Further, the CPRA was recently voted into law by California residents. The CPRA significantly amends the CCPA, and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA will go into effect on January 1, 2023, and become enforceable on July 1, 2023.

In Europe, the GDPR went into effect on May 25, 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the European Union, or EU, and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR, or UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the United Kingdom long term without additional measures. These changes may lead to additional costs and increase our overall risk exposure.

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 Endocrinology, 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), Ascendis Pharma Growth Disorders A/S (Denmark) and Ascendis Pharma Oncology Division A/S (Denmark). These subsidiaries are also set forth in Exhibit 8.1 to this annual report.

D. Property, Plant and Equipment

Our material tangible fixed assets relate to leased facilities, which are recognized and measured as right-of-use assets in the consolidated financial statements. We do not own any of our facilities.

Our corporate headquarters is located in Hellerup, Denmark. In addition, we have offices and research and development facilities in Germany and United States. 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. Accordingly, we engage with Contract Manufacturing Organizations, or CMOs, to manufacture clinical trial supply, as well as we enter into long term collaborations with CMOs to establish and maintain commercial-scale manufacturing processes for our product candidates and devices.

The following table specifies our leased facilities and their related activities.

Location	Size (in square meters)	Primary usage	Enforceable lease period	Option to extend the lease beyond enforceable lease period
Denmark				
Tuborg Boulevard, Hellerup	7,775	Corporate headquarters, administration and R&D	July, 2029	No
Tuborg Boulevard, Hellerup	1,567	Administration	January, 2037	No
Germany				

Location	Size (in square meters)	Primary usage	Enforceable lease period	Option to extend the lease beyond enforceable lease period
Technologiepark, Heidelberg	2,134	R&D and laboratory facilities	January, 2023	Rolling 24 months option to extend
Technologiepark, Heidelberg	480	R&D and laboratory facilities	December, 2021	No
Kurfürstendamm, Berlin	165	Clinical operations	May, 2022	No
United States				
University Avenue, Palo Alto, California,	465	Administration and clinical operations	March, 2021	No
Emerson Street, Palo Alto, California	1,134	Administration and clinical operations	April, 2022	No
Redwood City, California(1)	3,681	R&D and laboratory facilities	April, 2030	Option to extend for additional five years
Page Mill, Palo Alto, California(2)	6,765	Administration	October, 2033	Option to extend for up to two periods of five years each
West Windsor Township, New Jersey	1,097	Selling and administration	December, 2025	Option to extend for additional five years

(1) Our Redwood City location was established in connection with the development of the second therapeutic area, Oncology, which was established in January 2019. After entering the lease, significant leasehold improvements, primarily related to construction of laboratory facilities, were conducted. The Redwood City location has been in operation since May 2020.

(2) Our Page Mill lease commenced in November 2020, where its main activities will be general and administration functions, and clinical activities in the United States. During 2021, the Page Mill lease will undergo significant construction work. We expect the construction work will be completed in July 2021, after which we will take it into use.

We incepted two new leases in the fourth quarter of 2020, located at Tuborg Boulevard, Hellerup, Denmark where we will lease 436 and 1,167 square meters of office space. These two leases will commence and come into use in January 2021, and the second quarter of 2021, respectively. In addition, a new lease for laboratory facilities in Heidelberg, Germany is expected to commence in 2021.

We believe that our existing facilities together with the two new leases of office space 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 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 "Special Note Regarding Forward-Looking Statements" sections and elsewhere in this annual report.

A. Operating Results

Overview

For a description of business highlights in 2020, please refer to "Item 4B. Business Overview".

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 commercial product sales.

We had a net loss of €419 million for the year ended December 31, 2020 compared to a net loss of €218 million for the year ended December 31, 2019, and a net loss of €130.1 million for the year ended December 31, 2018. Our total equity was €838.7 million as of December 31, 2020 compared to €597.1 million as of December 31, 2019. We have not generated royalties or revenues from commercial product sales, and do not expect to generate such prior to regulatory approval of any of our product candidates.

Impact from COVID-19 Pandemic

A novel strain of coronavirus, ("COVID-19") was reported to have surfaced in Wuhan, China, in December 2019. Since then, COVID-19 has spread around the world into a pandemic, including into countries where we are operating, where we have planned or have ongoing clinical trials, and where we rely on third-parties to manufacture preclinical and clinical supplies, as well as commercial supply.

Since COVID-19 started to spread around the world, we have closely monitored the development, and implemented several measures to accommodate any potential negative impact on our business, and to ensure the safety of our employees, including:

- Encouraging employees to work remotely, reduce travel activity and minimize face-to-face meetings;
- Establishing home offices, and ensuring proper and secure IT infrastructure, enabling a safe and efficient remote work environment;
- Implementing remote visits for patients enrolled in our clinical trials, including ensuring safe delivery of clinical drugs;
- Establishing dedicated COVID-19 working groups to monitor and keeping close dialogue with manufacturing partners; and
- Establishing measures to accommodate sufficient capacity in logistics and manufacturing.

While COVID-19 has an impact on how we work and conduct our activities, we managed to avoid significant disruptions to our operations in 2020. Further, while COVID-19 continues to remain in the global society, we will keep working with COVID-19 measures to accommodate any business disruptions and to achieve our strategic objectives. Further, as a participant in the global fight against spreading the virus, we will maintain and further develop precautionary measures within our organization, including encouraging our employees to work remotely, reduce travel activity and minimize face-to-face meetings.

In addition, to accommodate efficient procedures for financial reporting, including internal controls, we have, also before the pandemic, structured our work environment, enabling our employees to perform their tasks remotely. Accordingly, it has not been necessary to make material changes to our internal control over financial reporting due to the pandemic.

While COVID-19 did not have a significant negative impact on our business in 2020, we foresee elevated COVID-19 related risks in certain areas, including:

- In conducting our clinical trials, there is a risk that suppliers experience delays in providing necessary equipment, consumables and services, which potentially could cause temporary delays in clinical trial activities. In addition, there is a risk that patients will elect not to enroll in trials to limit their exposure to medical institutions, which could potentially have a negative impact on clinical trial timelines;
- Global demand for COVID-19 vaccines could result in contract manufacturers not having sufficient capacity to meet scheduled manufacturing. In addition, sourcing of certain types of raw materials, consumables and equipment could result in scheduled manufacturing being delayed or postponed;
- Travel restrictions and local outbreaks of COVID-19 could restrict authorities from performing site inspections in connection with their review procedures of marketing applications for TransCon hGH (longapegsomatropin), which could potentially delay the commercial launch; and
- Our commercial launch strategy could be negatively impacted by patients not being able to see their physicians, and similarly, our commercial team not being able to meet with physicians, which could both have a negative impact on the commercial launch strategy.

We monitor these risks closely, and work with relevant stakeholders to avoid disruptions, and to develop and establish working measures. However, while COVID-19 continues to impact global societies, the uncertainty related to the duration and direction of the pandemic makes the future impact from COVID-19, including the magnitude of any impact on our operational results, highly uncertain and unpredictable.

For additional description related to COVID-19 related risks, please refer to “Item 3D. Risk Factors”.

Financial Operations Overview

Income and Expenses

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, including delivery of clinical supply material and feasibility studies performed for potential partners. We have not yet generated any revenue from commercial product sales.

Historically, we have, and we may in the future, enter into collaboration agreements, where timing of our operating cash flows may vary significantly from the recognition of the related revenue. Depending on the terms and conditions, revenue from up-front or initiation payments may be deferred and recognized as revenue over the period of continued involvement. Milestone payments are usually recognized as revenue only to the extent that it is highly probable that reversal will not occur, which substantially is when the uncertainty associated with the milestone payment is resolved, and we are entitled to the milestone payment. Service fees are recognized when the services have been performed. Clinical trial supply is recognized as revenue at the point in time that control of the goods is transferred to the customer.

Historically, our revenue has varied substantially, and may continue to vary, from quarter-to-quarter and year-to-year, depending upon, among other things, 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.

Our expenses relate to research and development activities and to selling, general and administration.

Research and development costs consist primarily of manufacturing costs, preclinical and clinical study costs performed by Clinical Research Organizations, or CROs, salaries and other personnel costs including pension and share-based payment, the cost of facilities, the cost of obtaining and maintaining the Company’s intellectual property portfolio, and depreciation of non-current assets used in research and development activities.

Selling, general and administrative expenses comprise salaries and other personnel costs including pension and share-based payment, office supplies, cost of facilities, and depreciation of non-current assets related to selling, general and administrative activities, and pre-commercial activities.

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. Accordingly, we engage with Contract Manufacturing Organizations, or CMOs, to manufacture clinical trial supply, as well as we enter into long term collaborations with CMOs to establish and maintain commercial-scale manufacturing processes for our product candidates and devices.

Operating Assets and Liabilities

Our operating assets and liabilities primarily relate to property, plant and equipment, prepayments and accruals for development costs, lease liabilities and trade payables. Property, plant and equipment primarily relate to leased facilities, which are recognized and measured as right-of-use assets in the consolidated financial statements. We do not own any of our facilities.

Since we have not generated any revenue from commercial product sales, we do not have any inventories or trade receivables from commercial product sales. Manufacturing of pre-launch inventories is initiated for late-stage product candidates and is recognized as inventories. However, since pre-launch inventories are not realizable prior to obtaining marketing approvals, pre-launch inventories are immediately written down to zero, through research and development costs. If the marketing approval is obtained, write-downs of pre-launch inventories will be reversed through research and development costs.

Capital Structure

The Company’s capital structure consists only of equity comprising issued capital, reserves and retained earnings/accumulated deficits. We did not have any interest-bearing debt for any of the periods presented in this annual report. As such, finance income and finance expenses consist primarily of interest income, interest expenses recognized for lease liabilities, and realized and unrealized exchange rate gains and losses on cash, cash equivalents, marketable securities, receivables and payables in foreign currencies. Accordingly, 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, British Pounds, and Danish Kroner. 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, 2020, 2019 and 2018:

	Year Ended December 31,		
	2020 (EUR'000)	2019 (EUR'000)	2018 (EUR'000)
Revenue	6,953	13,375	10,581
Research and development costs	(260,904)	(191,621)	(140,281)
Selling, general and administrative expenses	(76,669)	(48,473)	(25,057)
Operating profit/(loss)	**(330,620)**	**(226,719)**	**(154,757)**
Share of profit/(loss) in associate	(9,524)	(8,113)	(321)
Finance income	1,812	17,803	24,714
Finance expenses	(80,842)	(1,221)	(127)
Profit/(loss) before tax	**(419,174)**	**(218,250)**	**(130,491)**
Tax on profit/(loss) for the year	219	234	394
Net profit/(loss) for the year	**(418,955)**	**(218,016)**	**(130,097)**

Revenue

The following table summarizes our revenue for the years ended December 31, 2020, 2019 and 2018:

	Year Ended December 31,		
	2020 (EUR'000)	2019 (EUR'000)	2018 (EUR'000)
Revenue from the rendering of services (recognized over time)	2,140	9,919	1,215
Sale of clinical supply (recognized at a point in time)	2,206	804	—
"Right-to-use" licenses (recognized at a point in time)	2,607	2,652	9,366
Total revenue	**6,953**	**13,375**	**10,581**

Revenue for the year ended December 31, 2020 was €7.0 million, a decrease of €6.4 million, or 48%, compared to €13.4 million for the year ended December 31, 2019, and primarily comprised sale of clinical supply, rendering of services, and recognition of internal profit deferred from November 2018 when we entered into the collaboration with VISEN. The decrease was due to a lower amount of license and service revenue, partly offset by sale of clinical supply, to VISEN.

Revenue for the year ended December 31, 2019 was €13.4 million, an increase of €2.8 million, or 26%, compared to €10.6 million for the year ended December 31, 2018. The change was due to recognition of revenue related to our investment in VISEN, as well as sale of clinical supply to VISEN for use in clinical trials in Greater China.

Research and Development Costs

Research and development costs were €260.9 million for the year ended December 31, 2020, an increase of €69.3 million, or 36%, compared to €191.6 million for the year ended December 31, 2019.

External development costs related to TransCon hGH (lonapegsomatropin) increased by €2.9 million, primarily driven by increases in clinical trial costs and write-downs on pre-launch inventories related to lonapegsomatropin, as well as costs related to regulatory, statistical and medical activities related to the preparation of the BLA-filing, partly offset by lower costs for manufacturing of validation batches.

External development costs related to TransCon PTH increased by €8.6 million, reflecting increased clinical trial costs related to the progress of our phase 2 PaTH Forward clinical trial, increased costs of device development, and increased costs of biometric activities compared to last year.

External development costs related to TransCon CNP increased by €5.4 million, primarily reflecting an increase in manufacturing costs and clinical trial costs for our phase 2 ACcomplisH Trial, partly offset by a decrease in preclinical costs.

External development costs related to our oncology product candidates, primarily TransCon TLR7/8 Agonist and TransCon IL-2 b/g, increased by €14.1 million, reflecting an increase in manufacturing costs and preclinical costs as these product candidates progress through the early development stages and into manufacturing.

Other research and development costs increased by €38.3 million, primarily driven by an increase in personnel costs of €19.6 million and non-cash share-based payment of €10.6 million due to a higher number of employees in research and development functions, but also reflecting increases of €4.8 million in IT and telecommunication costs and €3.1 million in facility costs and depreciation allocated to research and development functions. Other costs, including laboratory operations, supplies and professional fees, increased by net €3.3 million compared to the same period last year. Travel and entertainment costs decreased by €3.1 million, primarily due to the COVID-19 pandemic. Research and development costs included non-cash share-based payment of €33.0 million for the year ended December 31, 2020, compared to €22.4 million for the year ended December 31, 2019.

Research and development costs were €191.6 million for the year ended December 31, 2019, an increase of €51.3 million, or 37% compared to €140.3 million for the year ended December 31, 2018.

External development costs to our TransCon hGH product candidate increased by €10.5 million, primarily driven by manufacturing of validation batches, or process performance qualification batches, and initial costs of pre-launch inventories, partly offset by a decrease in clinical trial costs, reflecting the completion of the phase 3 heiGHt Trial in the first quarter of 2019. The process performance qualification batches are required as part of the regulatory approval process with the FDA, and, as well as the pre-launch inventories, are recognized as development costs when incurred. However, after potential marketing approval, the products from these process performance qualification batches and pre-launch inventories may be used for commercial sales, thereby reducing the costs for the first period after market launch.

External development costs to our new therapeutic area within oncology increased by €3.7 million compared to the year ended December 31, 2018 and external development costs to our TransCon PTH product candidate increased by €1.9 million, primarily reflecting higher manufacturing and clinical trial costs. External development costs related to our TransCon CNP product candidate and other external development costs decreased by €0.3 million, primarily due to lower manufacturing and preclinical costs, partly offset by an increase in clinical trial costs, reflecting the phase 2 ACcomplisH Trial which was initiated in the third quarter of 2019.

Other research and development costs increased by €35.5 million, primarily driven by a €16.3 million increase in personnel costs and a €12.1 million increase in non-cash share-based compensation due to a higher number of employees in research and development functions, but also reflecting a €7.1 million increase in other costs, including a €2.3 million increase in facility costs allocated to research and development functions and a €1.8 million increase in travel costs to the increasing number of employees. Research and development costs included non-cash share-based payment of €22.4 million for the year ended December 31, 2019, compared to €10.2 million for the year ended December 31, 2018.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were €76.7 million for the year ended December 31, 2020, an increase of €28.2 million, or 58%, compared to €48.5 million for the year ended December 31, 2019. The higher expenses were primarily due to an increase in personnel costs of €10.3 million and non-cash share-based payment of €5.0 million for additional commercial and administrative personnel. IT and telecommunication costs increased by €4.8 million and insurance costs increased by €3.3 million. Professional fees, primarily related to building up our commercial capabilities, but also including legal costs and recruitment, increased by €5.6 million. Other costs, including facility costs and depreciation, increased by net €0.6 million, whereas travel and entertainment costs decreased by €1.4 million, primarily due to the COVID-19 pandemic. Selling, general and administrative expenses included non-cash share-based payment of €20.2 million for the year ended December 31, 2020, compared to €15.1 million for the year ended December 31, 2019.

General and administrative expenses were €48.5 million for the year ended December 31, 2019, an increase of €23.4 million, or 93%, compared to €25.1 million for the year ended December 31, 2018. The increase is primarily due to an increase in personnel costs of €6.6 million and non-cash share-based payment of €5.7 million for additional administrative personnel, but also reflecting increases of €4.0 million in IT costs and €1.0 million in travel costs. External costs related to pre-commercialization activities increased by €3.4 million. Other costs allocated to general and administrative functions increased by net €2.7 million, including facility costs and consultants. General and administrative expenses included non-cash share-based payment of €15.1 million for the year ended December 31, 2019, compared to €9.4 million for the year ended December 31, 2018.

Net Profit / (Loss) in Associate

Net loss in associate was €9.5 million for the year ended December 31, 2020 compared to €8.1 million for the year ended December 31, 2019, which represents the Company's share of net result in VISEN.

Net loss in associate was €8.1 million for the year ended December 31, 2019 compared to €0.3 million for the year ended December 31, 2018, which represent the Company's share of net result in VISEN which was established in November 2018.

Finance Income and Finance Expenses

Finance income was €1.8 million for the year ended December 31, 2020, a decrease of €16.0 million compared to €17.8 million for the year ended December 31, 2019. Finance expenses were €80.8 million for the year ended December 31, 2020, an increase of €79.6 million compared to €1.2 million for the year ended December 31, 2019. As we hold positions of marketable securities and cash and cash equivalents in U.S. Dollar, we are affected by exchange rate fluctuations when reporting our financial results in Euro. For the year ended December 31, 2020, we recognized an exchange rate loss when reporting our U.S. Dollar positions in Euro, reflecting negative exchange rate fluctuations, whereas we recognized a gain for the year ended December 31, 2019, reflecting positive exchange rate fluctuations, primarily between the U.S. Dollar and Euro. Further, the change reflects a €8.2 million decrease in interest income due to declining interest rates compared to last year, and a €0.7 million increase in interest expenses on lease liabilities.

Finance income was €17.8 million for the year ended December 31, 2019, a decrease of €6.9 million compared to €24.7 million for the year ended December 31, 2018. Finance expenses were €1.2 million for the year ended December 31, 2019, an increase of €1.1 million compared to €0.1 million for the year ended December 31, 2018. Interest income of €10.1 million for the year ended December 31, 2019 was €6.0 million higher than for the year ended December 31, 2018, whereas positive exchange rate fluctuations decreased from €20.7 million for the year ended December 31, 2018 to €7.7 million for the year ended December 31, 2019. Interest expenses increased from €0.1 million for the year ended December 31, 2018 to €1.2 million for the year ended December 31, 2019, primarily reflecting the recognition of interest expenses on lease liabilities.

We did not have any interest-bearing debt for any of the periods presented. However, IFRS 16, "Leases", requires interest expenses to be recognized on lease liabilities.

Tax on Profit / (Loss) for the Year

Tax for the year ended December 31, 2020 was a net credit of €0.2 million, in line with the net credit of €0.2 million for the year ended December 31, 2019. 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, 2020, the jointly taxed Danish entities had a tax loss, and accordingly were entitled to a tax refund of approximately €0.7 million, partly offset by tax provisions of €0.4 million in our German subsidiary and €0.1 million in one of our subsidiaries in the United States.

Tax for the year ended December 31, 2019 was a net tax credit of €0.2 million, compared to a net tax credit of €0.4 million for the year ended December 31, 2018. For the year ended December 31, 2019, 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, 2019 further comprised a tax provision of €0.4 million related to our subsidiary in Germany and a net tax provision of €0.1 million related to our subsidiary in the United States.

At December 31, 2020, 2019 and 2018, we had net deferred tax assets of €235.0 million, €128.9 million, and €78.5 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.

Critical Accounting Policies, Judgements, Estimates and Assumptions

Our consolidated financial statements have been prepared in accordance with IFRS as issued by the IASB. A description of our critical accounting policies is provided in the Accounting Policies section of the audited consolidated financial statements as of and for the years ended December 31, 2020, 2019 and 2018 included elsewhere in this annual report.

Significant Accounting Judgements, Estimates and Assumptions

In the application of the Company's accounting policies, we are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. Judgements and estimates applied are based on historical experience and other factors that are relevant, and which are available at the reporting date. Uncertainty concerning judgements and estimates could result in outcomes, that require a material adjustment to assets and liabilities in future periods.

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. While the application of critical accounting estimates is subject to material estimation uncertainties, our ongoing revisions of critical accounting estimates have not revealed any material impact in any of the years ended December 31, 2020, 2019 or 2018.

Significant accounting judgements, estimates and assumptions, which may have a material impact on the consolidated financial statements, are described in following sections.

Revenue

Revenue is primarily generated from collaboration and license agreements, which typically involve multiple promises, and thus require significant judgements by management 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 judgements relating to specific revenue transactions are described below.

Identifying Performance Obligations and Allocating Transaction Price

Three license agreements with the Company's associate VISEN, or licensee, grant the licensee exclusive rights to develop, manufacture, and commercialize patented product candidates in Greater China, including the right to grant sub-licenses to third parties. In addition to the licenses, the Company will provide development services and deliver clinical supply material for clinical trials within Greater China.

In determination of the performance obligations under the license agreements, the stand-alone values of the promises and the Company's responsibility in the development activities, have been considered. Since licensed product candidates were all in phase 1 clinical trials or later stages of development, the licensee can benefit from each promise in the contract either on their own or together with readily available resources. Accordingly, licenses, development services, and clinical trial supplies are all considered distinct performance obligations.

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

Management has considered whether the Company is obligated or expected to perform research and development activities that significantly affect the licensee's ability to benefit from product candidates. If the Company is contractually obligated, or is 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". Since licensed products are patented drug formulas, future activities do not affect their stand-alone functionalities. Accordingly, all three licenses 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 consolidated statement of profit or loss and financial position, the effects of share-based payment transactions. Warrant compensation costs are recognized as research and development costs or as selling, general and administrative expenses, as appropriate, over the vesting period, based on management's best estimate of the number of warrants that will ultimately vest, which is subject to uncertainty. In addition, warrant compensation costs are measured according to grant date fair values of the warrants granted. Estimating fair values requires the Company to apply generally accepted valuation models, and apply these models consistently according to the terms and conditions of the specific warrant program. Under all warrant programs, the Black-Scholes option-pricing model has been applied to determine the fair value of warrants granted. Subjective judgements and assumptions, which are subject to estimation uncertainties, need to be exercised in determining the appropriate input to the valuation model.

Warrant compensation cost recognized in the consolidated statement of profit or loss was €53.2 million, €37.5 million and €19.7 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Internally Generated Intangible Assets

Development of Drug Candidates

IAS 38, "Intangible Assets" prescribes that intangible assets arising from development projects must be recognized in the consolidated statements of financial position 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 the Company has the intent to produce and market the product. Such an intangible asset shall be recognized if it can be demonstrated 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 related to drug candidates cannot be determined with sufficient certainty until the development activities have been completed and the necessary marketing approvals have been obtained. Accordingly, the Company does not recognize internally generated intangible assets at this time.

Joint Arrangements

Collaboration and license agreements within the Company's industry are often structured so that each party contributes its respective skills in the various phases of a development project, and significant judgement is required by management to determine whether collaboration agreements comprise customer/supplier relationship or joint arrangements where parties share risks and rewards.

It has been concluded that no joint control exists for the Company's license agreements and the parties do not have any financial obligations on behalf of each other. Accordingly, since neither of the license agreements are considered to be joint arrangements, these are classified as contracts with customers.

Pre-launch Inventories

In order to accommodate market demands, the Company initiates manufacturing of inventories for late-stage development product candidates prior to obtaining marketing approvals, or pre-launch inventories.

In determining the accounting for pre-launch inventories, management considers the probability of future benefits, and accordingly, whether pre-launch inventories qualify as assets. Manufacturing of pre-launch inventories are initiated for late-stage product candidates and are recognized as inventories. However, since pre-launch inventories are not realizable prior to obtaining marketing approvals, pre-launch inventories are immediately written down to zero, through research and development costs. If the marketing approval is obtained, write-downs of pre-launch inventories will be reversed through research and development costs.

Accruals and Prepayments on Project Development Cost

Development of drug candidates requires spend of significant resources, and establishment of long-term working relationships with CROs and CMOs. Work performed by CROs and CMOs and other project suppliers, often comprise deliveries for more than one reporting period, and where payment terms for contractual work not necessarily reflect the stage of completion of the individual projects and activities. Accordingly, determination of the stage of completion for ongoing project activities include estimation uncertainties as future efforts to complete the specific activity may be difficult to predict.

On each reporting date, all significant ongoing activities are reviewed to determine the stage of completion and compared to the invoices received. Accruals are recognized for individual projects where the stage of completion exceeds the costs of invoices received. Similarly, prepayments are recognized for invoiced costs in excess of the stage of completion. We have implemented accrual calculation models and policies, to ensure that consistent accrual procedures are applied, which includes analyzing significant project stages and payment structures, comparing project milestones to planned performance, and revisiting prior periods estimates.

As of December 31, 2020, the consolidated statement of financial position included prepaid project costs of €10.5 million and accrued project costs of €17.0 million, compared to €5.8 million and €10.5 million, respectively, as of December 31, 2019.

Leases

Determination of Lease Term

Certain lease arrangements provide the Company with contractual rights (not obligations) to either extend the lease after the initial term, or not to terminate the lease within the enforceable lease term, i.e., periods where lessor cannot terminate the lease. Those options cover periods in the range from two to ten years in addition to the non-cancellable periods. Significant judgement is required by management to determine whether it is reasonably certain to exercise an extension option, or not to exercise a termination option, upon occurrence of an event of change in circumstances, that is within the control of the Company.

Except for the above areas, assumptions and estimates are not considered to be critical to the consolidated financial statements.

Quantitative and Qualitative Disclosures about Market Risk

Our activities 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. We have received payments in U.S. Dollars under our collaborations and the proceeds from our Series D financing in November 2014, our IPO in February 2015 and our follow-on offerings, the latest being in July 2020, were also 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 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, 2020, the net carrying amount of our monetary assets and liabilities was €702.1 million, where the direct exposure from U.S. Dollar (U.S Dollar monetary assets and liabilities held by non-U.S.Dollar entities) was €797.9, which primarily related to the proceeds from the follow-on offering completed in July 2020, and marketable securities.

A sensitivity analysis of our exposure to the U.S. Dollar based on outstanding foreign currency denominated monetary items as of December 31, 2020 shows that a strengthening of the U.S. Dollar against the Euro by 10% would increase profit or loss and equity before tax by €79.8 million. A 10% weakening of the U.S. Dollar against the Euro would decrease profit or loss and equity before tax by a similar amount.

Interest Rate Risk

We have no interest-bearing debt to third parties. In addition, while we hold no derivatives or financial assets and liabilities measured at fair value, the exposure to interest rate risk primarily relates to the interest rates for cash, cash equivalents and marketable securities. Future interest income from interest-bearing bank deposits and marketable securities may fall short of expectations due to changes in interest rates.

The effects of interest rate fluctuations are not considered a material risk to the Company’s financial position. Accordingly, no interest sensitivity analysis has been presented.

Credit Risk

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

All material counterparties are considered creditworthy. While the concentration of credit risk may be significant, the credit risk for each individual counterpart is considered to be low. Our exposure to credit risk primarily relates to cash, cash equivalents, and marketable securities. The credit risk on our bank deposits is limited because the counterparties, holding significant deposits, are banks with high credit-ratings (minimum A3/A-) assigned by international credit-rating agencies. The banks are reviewed on a regular basis and deposits may be transferred during the year to mitigate credit risk. On each reporting date, we consider the risk of expected credit loss on bank deposits, including the hypothetical impact arising from the probability of default, which is considered in conjunction with the expected loss caused by default by banks with similar credit ratings and attributes. In line with previous periods, this assessment did not reveal a material impairment loss, and accordingly no provision for expected credit loss has been recognized.

Since March 2020, in order to mitigate the concentration of credit risks on bank deposits and to preserve capital, a portion of our bank deposits have been placed into primarily U.S. government bonds, treasury bills, corporate bonds, and commercial papers. Our investment policy, approved by the Board of Directors, only allows investment in marketable securities having investment grade credit-ratings, assigned by international credit-rating agencies. Accordingly, the risk and probability of default is low. The risk of expected credit loss on marketable securities has been considered, including the hypothetical impact arising from the probability of default, which is considered in conjunction with the expected loss caused by default on securities with similar credit rating and attributes. This assessment did not reveal a material expected credit loss, and accordingly no provision for expected credit loss has been recognized.

For other financial assets, including deposits and receivables, the credit risk is considered low and no provision for expected credit loss has been recognized.

B. Liquidity and Capital Resources

Our liquidity and capital resources comprise cash, cash equivalents and marketable securities.

As of December 31, 2020, these amounted to €834.1 million, and are specified as follows:

	Carrying amount	Fair value
	(EUR'000)	
December 31, 2020		
Liquidity and capital resources		
Marketable securities	249,558	249,530
Cash and cash equivalents	584,517	584,517
Total liquidity and capital resources	**834,075**	**834,047**
Classification in consolidated statement of financial position		
Non-current assets	115,280	115,277
Current assets	718,795	718,770
Total liquidity and capital resources	**834,075**	**834,047**

Marketable securities have a weighted average duration of 6.0 and 17.3 months, for current (i.e., those maturing within twelve months after the reporting date) and non-current positions, respectively. The entire portfolio of marketable securities (current and non-current) has a weighted average duration of 11.2 months.

We have historically funded our operations primarily through issuance of our preference shares, ordinary shares, 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.

In February 2015, we announced the closing of our initial public offering, with net proceeds of $111.5 million (or €101.4 million). In addition, we have completed follow-on public offerings of American Depositary Shares, or ADSs, as specified below (all amounts disclosed after deducting underwriters' commissions and offering expenses):

- In 2016, with net proceeds of $127.1 million (or €116.6 million);
- In 2017, with net proceeds of $145.2 million (or €123.1 million);
- In 2018, with net proceeds of $242.5 million (or €198.6 million);
- In 2019, with net proceeds of $539.4 million (or €480.3 million); and
- In July 2020, with net proceeds of $654.6 million (or €580.5 million).

Since our inception, until December 31, 2020, we have funded our operations through the sale of €1,830.2 million of our preference shares, ordinary shares and convertible debt securities, including our IPO, follow-on offerings and exercise of warrants.

In addition, we have historically received cash proceeds under collaboration and license agreements, which are structured as upfront fees for out-licensing of technology and assignment of certain intellectual property rights, and for services rendered under those agreements. In addition, we have received cash proceeds through feasibility studies, where potential partners evaluate if TransCon technologies enable 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.

Cash requirements

We maintain cash-forecasts to ensure sufficient cash reserves are available to settle liabilities as they fall due. Cash reserves should be in place to support the daily operations and strategic objectives to support clinical trials and other development activities in line with our corporate objectives.

As of December 31, 2020, our cash requirements primarily relate to following:

- lease obligations, related to our office and research and development facilities, which are recognized as lease liabilities in the consolidated statement of financial position;
- construction of property, plant and equipment, including leasehold improvements;
- purchase obligations, under our commercial supply agreements and related activities;
- research and development activities related to clinical trials for our product candidates in clinical development.

The length of leases varies from two to eleven years, without considering optional extension periods. Our cash requirements for our lease obligations (on an undiscounted basis) are €7.0 million and €106.8 million, for the short-term (payable within twelve months after the reporting date) and long-term (payable beyond twelve months after the reporting date), respectively. In addition, our lease obligations establish ancillary contractual commitments in relation to utilities, maintenance, levies, and other services. Costs relating to those commitments are recognized as services are received.

Obligations related to property, plant and equipment which include construction of leasehold improvements amounts to €15.8 million and is partly subject to reimbursement from one lessor. The work is expected to be finalized and settled in 2021.

We have also entered into long-term commercial supply agreements, to support the commercial manufacturing of TransCon hGH (lonapegsomatropin), which include purchase obligations, usually determined on binding and non-binding supply forecasts, that are subject to continuous negotiation and adjustments according to the individual contractual terms and conditions. Cash requirements for those purchase obligations are €91.0 million and €39.1 million, for the short-term and long-term, respectively.

As part of our ordinary activities, we engage third-party CROs to perform clinical trial activities, which are primarily studies for more than one year. We are not subject to contingent liabilities from potential milestone payments related to licensing of intellectual property.

We have not entered into any off-balance sheet arrangements or any holdings in variable interest entities. In addition, we are not aware of any significant legal claims or disputes.

Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities as of December 31, 2020 will be sufficient to meet our projected cash requirements for at least twelve 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:

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

- our ability to collect payments which are due to us from collaboration partners (if any), which in turn is impacted by the financial standing of any such 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 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 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.

The following table summarizes our cash flows for the years ended December 31, 2020, 2019 and 2018:

	Year Ended December 31,		
	2020 (EUR'000)	2019 (EUR'000)	2018 (EUR'000)
Cash flows from/(used in) operating activities	(271,548)	(175,936)	(138,802)
Cash flows from/(used in) investing activities	(291,199)	(5,159)	(2,648)
Cash flows from/(used in) financing activities	602,650	493,593	203,267
Net increase in cash and cash equivalents	**39,903**	**312,498**	**61,817**

Cash flows from/(used in) Operating Activities

Cash flows used in operating activities for the year ended December 31, 2020 was €271.5 million compared to €175.9 million for the year ended December 31, 2019. The net loss for the year ended December 31, 2020 of €419.0 million included non-cash charges of €62.6 million, comprising share-based payment and depreciation, non-cash revenue of €3.5 million, and non-cash net financial expenses and taxes, of €89.3 million. The net change in working capital contributed negatively to cash flows by €1.0 million, primarily due to an increase in prepayments of €6.4 million, an increase in receivables of €2.0 million and a decrease in contract liabilities of €0.5 million, partly offset by an increase in trade payables, accrued expenses and other payables of €7.9 million.

Cash flows used in operating activities for the year ended December 31, 2019 was €175.9 million compared to €138.8 million for the year ended December 31, 2018. The net loss for the year ended December 31, 2019 of €218.0 million included non-cash charges of €44.2 million, comprising share-based payment and depreciation, and non-cash net income, including net financial income and taxes, of €6.2 million. The net change in working capital contributed positively to cash flows by €4.1 million, primarily due to a net increase in trade payables and other payables of €7.5 million, and a decrease in prepayments of €4.8 million, partly offset by a decrease in deferred income of €6.0 million and an increase in receivables and deposits of €2.2 million.

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 Investing Activities

Cash flows used in investing activities for the year ended December 31, 2020 of €291.2 million were related to acquisition of marketable securities of €537.8 million and settlement of marketable securities of €263.1 million, to acquisition of property, plant and equipment of net €14.8 million, primarily related to our oncology laboratories in the U.S. and for use in the laboratories of our German facility, and to development of software of €1.7 million.

Cash flows used in investing activities for the year ended December 31, 2019 of €5.2 million were related to acquisition of property, plant and equipment, primarily equipment for use in the laboratories of our German facility and in our oncology laboratories in the U.S.

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 from / (used in) Financing Activities

Cash flows from financing activities for the year ended December 31, 2020 of €602.7 million were comprised of €580.5 million in net proceeds from our follow-on public offering of ADSs completed in July 2020 and €26.9 million in net proceeds from warrant exercises in April, May, June, August, September, November and December 2020, partly offset by payments on lease liabilities of €4.8 million.

Cash flows from financing activities for the year ended December 31, 2019 of €493.6 million were comprised of €480.3 million in net proceeds from our follow-on public offering of ADSs completed in March 2019 and €17.3 million in net proceeds from warrant exercises in April, June, September, November and December 2019, partly offset by payments on lease liabilities of €4.0 million.

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.

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

See “Item 4 B. Information on the Company—Business Overview” and “Item 5 A. Operating and Financial Review and Prospects – 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.

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, 2020. 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.	49	Chairman and Senior Vice President, Chief Legal Officer	2021
Lisa Bright	53	Board Member	2021
Albert Cha, M.D., Ph.D.	48	Board Member	2022
James I. Healy, M.D., Ph.D.	55	Board Member	2021
Jan Møller Mikkelsen	61	President, Chief Executive Officer, Board Member and Executive Director	2021
Birgitte Volck, M.D., Ph.D.	58	Board Member	2022
Lars Holtug	62	Board Member	2022

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. Previously, she served as President International for Intercept Pharmaceuticals, Inc., a biopharmaceutical company, from July 2016 to January 2021. 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 the board of directors since November 2014. Dr. Cha is a Managing Partner with Frazier Healthcare Partners. He previously was a managing partner at Vivo Capital LLC, 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 KalVista Pharmaceuticals, Inc. (NASDAQ: KALV) 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 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, Sierra Oncology, Inc., a publicly traded oncology company, Biohaven Pharmaceutical Holding Company Ltd, a publicly traded clinical-stage biopharmaceutical company targeting neurological diseases and Menlo Therapeutics, Inc., a publicly traded late-stage biopharmaceutical company focused on the treatment of pruritus. 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 Investments, Inc. (formerly Sofinnova Ventures), a venture capital firm, since June 2000. Prior to June 2000, Dr. Healy held various positions at Sanderling Ventures, Bayer Healthcare Pharmaceuticals (as successor to Miles Laboratories) and ISTA Pharmaceuticals, Inc. Dr. Healy is currently on the board of directors of Bolt Therapeutics, Inc. (Nasdaq: BOLT), Coherus BioSciences, Inc. (Nasdaq: CHRS), Karuna Therapeutics, Inc. (Nasdaq: KRTX), Natera, Inc. (Nasdaq: NTRA), NuCana plc (Nasdaq: NCNA), ObsEva SA (Nasdaq: OBSV) and Y-mAbs Therapeutics, Inc. (Nasdaq: YMAB) and two private companies. Previously, he served as a board member of Amarin Corporation, Auris Medical Holding AG, Edge Therapeutics, Inc., Hyperion Therapeutics, Inc., InterMune, Inc., Iterum Therapeutics PLC, 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. Dr. Volck served as the President of Research and Development at Avrobio Inc., from December 2017 to October 2020. From June 2016 to August 2018, Dr. Volck served as head of Research and Development, Rare Diseases for GlaxoSmithKline plc. From 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 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 June 2019, Dr. Volck serves as a non-executive director at Soleno Therapeutics. From May 2017 to June 2018, Dr. Volck served as a non-executive director for Wilson Therapeutics AB, a biotechnology company. From May 2016 to April 2019, 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 eleven subsidiaries, and of MTI Caretag ApS, a company investing in healthcare technology. Mr. Holtug also currently serves as a board member of Frida Forsikring Agentur A/S and Domus Forsikring A/S, as well as the Audit Committee Chair of the board of Domus Forsikring A/S. 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, 2020. 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	61	President, Chief Executive Officer, Board Member and Executive Director
Flemming Steen Jensen	59	Senior Vice President, Product Supply
Michael Wolff Jensen, L.L.M.	49	Chairman and Senior Vice President, Chief Legal Officer
Peter Rasmussen	52	Vice President, Finance and Principal Accounting Officer
Scott T. Smith	47	Senior Vice President, Chief Financial Officer
Lotte Sønderbjerg	59	Senior Vice President, Chief Administrative Officer
Kennett Sprogøe, Ph.D.	42	Senior Vice President, Head of Innovation and Research
Juha Punnonen, M.D., Ph.D.	55	Senior Vice President, Head of Oncology
Jens Sigurd Okkels	60	Senior Vice President, Product Development
Vibeke Miller Breinholt, Ph.D.	54	Senior Vice President, Nonclinical Development and Bioanalysis
Dana Pizzuti, M.D.	65	Senior Vice President, Development Operations
Mark Bach, M.D., Ph.D.	64	Senior Vice President, Clinical Development and Medical Affairs for Endocrine Medical Sciences
Jesper Høiland	60	Senior Vice President, Global Chief Commercial Officer

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 President and Chief Executive Officer as well as Board member since December 2007 and currently serves on the board of Visen. From 2002 to 2006, Mr. Mikkelsen served as President and Chief Executive Officer of LifeCycle Pharma A/S, now Veloxis Pharmaceuticals A/S, which was 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 and Quality 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 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 Officer since June 2013 and currently serves on the board of Visen. 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 LifeCycle Pharma, currently known as 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 Vicore Pharma AB. Mr. Jensen received an L.L.M. degree from the University of Copenhagen.

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 graduated magna cum laude with a 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, Mrs. 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, Mrs. 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, Mrs. Sønderbjerg was the Executive Secretary for the CEO and Board of Directors of Novo Nordisk A/S. Mrs. 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, Head of Innovation and Research since 2019, Senior Vice President of Product Innovation since January 2016 and Vice President Product Innovation since June 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.

Juha Punnonen, M.D., Ph.D. has served as our Senior Vice President, 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 (now 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 of Product Development since April 2019. Most recently, Dr. Okkels led an independent consulting firm in the biopharmaceutical industry, Okkels Consulting, GmbH. Prior to this, he served as Vice President, Head of the Chemistry, Manufacturing and Controls Center in Europe at Takeda, where he was responsible for numerous projects at all stages of development, from preclinical and launch to life cycle management. Prior to his tenure at Takeda, Dr. Okkels held multiple VP roles at Nycomed, including Vice President of Technical Development, the Biologics Network and the International Pharmaceutical Affairs. Dr. Okkels also served as the Science and Technology Director at Maxygen after a merger with ProFound Pharma, a company which he co-founded in 1999. He launched his industry career at Novo Nordisk in 1992 after completing his postdoctoral training at the Royal Veterinary and Agricultural University (RVAU). Dr. Okkels received his Ph.D. in biochemistry and molecular biology from the RVAU in Copenhagen, Denmark.

Vibeke Miller Breinholt, Ph.D. has served as our Senior Vice President of Nonclinical Development and Bioanalysis since January 2020 and Vice President of Nonclinical Development since January 2016. Dr. Breinholt has more than 15 years of experience within nonclinical development in the biopharmaceutical industry and more than seven years of experience in experimental cancer research. Prior to joining Ascendis Pharma, Dr. Breinholt served in roles of increasing responsibility at Novo Nordisk from November 2013 to December 2015, including serving as Head of Biopharm Toxicology and Safety Pharmacology, where she was responsible for overseeing more than 30 projects in early and late-stage development within diabetes, obesity, hemophilia and growth hormone deficiency. Prior to Novo Nordisk, she held positions of increasing responsibility at Genmab from October 2007 to November 2013, ending her tenure as Senior Director of Preclinical Safety and Preclinical Regulatory Affairs. While at Genmab, she led development activities across both inflammatory and immuno-oncology projects, including the regulatory documentation and strategy for first-in-human and later stage clinical trials. Dr. Breinholt began her industry career at Maxygen in October 2003, where she served as Head of Toxicology and Associate Director Regulatory affairs until October 2007. Dr. Breinholt received her M.S. and Ph.D. in Toxicology from Oregon State University within experimental cancer research and a B.S. in Bromatology from the Royal Veterinary and Agricultural University, Denmark. Dr. Breinholt also earned advanced diplomas in business administration and pharmaceutical regulatory affairs.

Dana Pizzuti, M.D. has served as our Senior Vice President of Development Operations since January 2020 and Vice President of Global Regulatory Affairs since July 2019. Dr. Pizzuti has more than 30 years of pharmaceutical industry experience in clinical development, pharmacovigilance, medical and regulatory Affairs. Prior to joining Ascendis Pharma, Dr. Pizzuti served as Senior Vice President of Regulatory Affairs, Quality and Pharmacovigilance at Theravance Biopharma, Inc., a biotechnology company, from March 2019 to July 2019 and served as Senior Vice President of Regulatory Affairs and Quality at Rigel Pharmaceuticals, a biotechnology company, from June 2017 to March 2019. Prior to Rigel, Dr. Pizzuti served as Vice President of Regulatory Affairs at Gilead Sciences, a pharmaceutical company, from March 2007 to June 2017, where she directly supervised a global regulatory department of more than 500 individuals in 33 countries and was responsible for obtaining marketing authorizations for 15 new drugs in global markets. Prior to Gilead, she served as Vice President of Global Regulatory Affairs for West Coast Pharmaceuticals at Johnson and Johnson and Vice President of Global Pharmacovigilance and Labeling at Bristol-Myers Squibb. For ten years, she held positions of increasing responsibility in Medical Affairs at Abbott Laboratories, ending her tenure there as Vice President of Global Medical Affairs for the Pharmaceutical Products Division and Abbott International. Dr. Pizzuti began her career in industry at Hoffmann-La Roche. She received her M.D. from New York University and a B.S. in Biology (cum laude) from Yale University.

Mark Bach, M.D., Ph.D. has served as our Senior Vice President of Clinical Development and Medical Affairs for Endocrine Medical Sciences since November 2020. Dr. Bach is a pediatric endocrinologist with 30 years of clinical research and pharmaceutical development experience, including extensive global experience building and leading clinical teams that have successfully launched innovative pharmaceutical products into global markets. Most recently, from August 2019 to October 2020, Dr. Bach served as interim CEO and previously led a team to design and establish Accumulus Synergy, Inc, a cross-industry initiative to design and build a cloud-based platform to facilitate data exchange between pharmaceutical companies and health authorities. Prior to this, Dr. Bach was based in Asia, and served as Head of Asia Pacific Medical Sciences at Janssen Pharmaceutical Co. from November 2014 to August 2019. Previously, he was Vice President of Research & Development and Scientific Affairs for Janssen Pharmaceutical KK in Japan from January 2010 to November 2012. For 16 years, he held positions of increasing responsibility in Clinical Research at Merck & Co., Inc., ending his tenure there as Vice President of Clinical Research Operations Worldwide. Dr. Bach has lectured in national and international forums, has numerous publications and served on professional society advisory boards to advance the field of endocrinology and clinical research. Dr. Bach received his M.D. from Baylor College of Medicine; his Ph.D. in Pathology from the University of Chicago; and his B.A. in Chemistry from the Carleton College.

Jesper Høiland has served as our Senior Vice President and Global Chief Commercial Officer since May 2020. He has over 25 years of senior leadership experience in operations, commercialization and global marketing and has launched five products to market leadership positions in endocrinology and hematology. Previously, he served as President and Chief Executive Officer of Radius Health from July 2017 to April 2020, where he led Tymlos® to a market leadership position in three years as a treatment for osteoporosis. Prior to joining Radius, Mr. Høiland served as Executive Vice President at Novo Nordisk and President of Novo Nordisk USA, overseeing approximately 5,300 employees from 2013 to 2016. Before serving as President of Novo Nordisk USA, Mr. Høiland held multiple global roles of increasing responsibility at Novo Nordisk from 1987 to 2013, including leading its International Operations. His extensive experience establishing global leadership of endocrinology products began with the first launch of Novo Nordisk’s daily growth hormone in 1988. Mr. Høiland holds an MSc in Management from Copenhagen Business School.

B. Compensation

Compensation of Members of Our Board of Directors and Senior Management

During 2020, Dr. Cha received board fees in the amount of €36,510 for his membership on our board and €17,342 for his tenure on the remuneration committee and the nominating and corporate governance committee, Dr. Healy received €36,510 for his membership on our board and €18,255 for his tenure on the nominating and corporate governance committee and the audit committee, Ms. Volck received €33,720 for her membership on our board and €4,215 for her tenure on the nominating and corporate governance committee, Ms. Bright received €33,720 for her membership on our board and €13,910 for her tenure on the audit committee and the remuneration committee, and Mr. Holtug received €33,720 for his membership on our board and €22,340 for his tenure on the audit committee and the remuneration committee. 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 December 10, 2020, Dr. Cha, Dr. Healy, Dr. Volck, Ms. Bright and Mr. Holtug were each granted 6,420 warrants, in each case with an exercise price per share of $176.28 (€145.5045) and an expiration date of December 10, 2030. The aggregate grant date fair value of the warrants granted to our board members in 2020 for their services as board members was €2,171,796.

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 2020, consisting of Messrs. Mikkelsen, Smith, Michael Wolff Jensen, Rasmussen, Flemming Steen Jensen, Høiland and Larson, Ms. Sønderbjerg and Drs. Sprogøe, Okkels, Punnonen, Breinholt, Pizzuti and Bach for the fiscal year ended December 31, 2020 was approximately €28.3 million. This amount consists of: (i) short-term employee benefits including salary and other in-kind benefits of approximately €4.5 million, (ii) bonuses of €3.2 million, (iii) share-based payments of approximately €20.3 million, and (iv) post-employment and other benefits of €0.3 million. Share-based payments reflect the 2020 expenses of warrants granted in or before 2020. During 2020, the board made the following warrant grants to members of our senior management who were employed by our company during 2020:

Name	Grant Date	Shares Subject to Awards Granted	Award Exercise Price(s)		Award Expiration Date
Vibeke Miller Breinholt	January 14, 2020	34,000	$138.82	(€124.8943)	January 14, 2030
Vibeke Miller Breinholt	December 10, 2020	22,755	$176.28	(€145.5045)	December 10, 2030
Dana Pizzuti	January 14, 2020	40,000	$138.82	(€124.8943)	January 14, 2030
Dana Pizzuti	December 10, 2020	22,755	$176.28	(€145.5045)	December 10, 2030
Jesper Høiland	June 6, 2020	90,000	$141.64	(€125.4117)	June 6, 2030
Jesper Høiland	December 10, 2020	15,170	$176.28	(€145.5045)	December 10, 2030
Mark A. Bach	November 10, 2020	54,000	$161.58	(€136.8389)	November 10, 2030

Sigurd Okkels	December 10, 2020	22,755	$ 176.28	(€145.5045)	December 10, 2030
Juha Punnonen	December 10, 2020	22,755	$ 176.28	(€145.5045)	December 10, 2030
Jan Møller Mikkelsen	December 10, 2020	101,145	$ 176.28	(€145.5045)	December 10, 2030
Scott T. Smith	December 10, 2020	22,755	$ 176.28	(€145.5045)	December 10, 2030
Michael Wolff Jensen	December 10, 2020	22,755	$ 176.28	(€145.5045)	December 10, 2030
Lotte Sønderbjerg	December 10, 2020	22,755	$ 176.28	(€145.5045)	December 10, 2030
Flemming Steen Jensen	December 10, 2020	22,755	$ 176.28	(€145.5045)	December 10, 2030
Kennett Sprogøe	December 10, 2020	22,755	$ 176.28	(€145.5045)	December 10, 2030
Peter Rasmussen	December 10, 2020	5,060	$ 176.28	(€145.5045)	December 10, 2030

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, 2020 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 twelve 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 twelve months' notice.

The agreements with Messrs. Michael Wolff Jensen and Flemming Steen Jensen and Ms. Lotte Sønderbjerg 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, 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 Mr. 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. 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 Drs. Okkels and Breinholt provide that the notice period may be no less than the notice required pursuant to the rules of the Danish Salaried Employees Act, which is at any time mutually extended by both parties with two months notice to the end of a month, provided that the executive may terminate with one month's notice in the case of certain conditions related to sickness. The agreements with certain of the foregoing senior management contain post-termination non-competition covenants that generally may last for a period of twelve months post-termination and entitle the executives to their base salary, or portion thereof, during the period.

The agreements with Messrs. Høiland and Smith and Drs. Bach, Pizzuti and Punnonen provide that their employment is at-will and may be terminated by either the executive or us at any time, provided that all the agreements other than the agreement with Mr. Smith contain a termination notice period of 60 days for a termination by the executive. However, the agreements with Messrs. Høiland and Smith and Drs. Bach and Pizzuti provide that in the event the executive is terminated by us without "cause" or he or she resigns for "good reason" (each, as defined in the agreements), the executive 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. Such severance period commences on the date of termination and ends as follows for each executive: for Mr. Høiland, the later of the first anniversary of the effective date of his employment agreement or the six-month anniversary of the date of termination; for Mr. Smith, the six-month anniversary of the date of termination; for Dr. Bach, the later of the first anniversary of the effective date of his employment agreement and three-month anniversary of the date of termination; and for Dr. Pizzuti, the six-month anniversary of the date of termination. In addition, for each of the executives, in the event of the executive's termination due to disability, he or she will be eligible to receive continued base salary and healthcare coverage for 120 days following termination, and in the event of his or her death, we will pay his or her estate a lump sum amount equal to three months of his or her 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 682,509 warrants in the period ending May 28, 2025.

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. 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 403,467 outstanding warrants, granted in the period 2012 to 2014, 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 52,323 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 5,772,274 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, 2021.

	Grant Date	Awards granted and outstanding	Awards granted and outstanding, but unvested as of March 1, 2021	Award Exercise Price(s)	Award Expiration Date
Jan Møller Mikkelsen	December 3, 2012	279,372	—	€7.9962	21 days following our interim report (six-month report) in 2023
	November 26, 2014	31,624	—	€6.4775	21 days following our interim report (nine-month report) in 2023

	December 18, 2015	217,000	—	€ 15.6750	December 18, 2025
	December 14, 2016	180,000	—	€ 19.4194	December 14, 2026
	December 12, 2017	200,000	41,667	€ 31.5995	December 12, 2027
	December 11, 2018	200,000	91,667	€ 54.6357	December 11, 2028
	December 10, 2019	120,000	85,000	€ 97.4993	December 10, 2029
	December 10, 2020	101,145	96,931	€145.5045	December 10, 2030
James I. Healy, M.D., Ph.D.	December 18, 2015	35,000	—	€ 15.6750	December 18, 2025
	December 14, 2016	15,000	—	€ 19.4194	December 14, 2026
	December 12, 2017	15,000	—	€ 31.5995	December 12, 2027
	December 11, 2018	13,000	—	€ 54.6357	December 11, 2028
	December 10, 2019	7,500	3,125	€ 97.4993	December 10, 2029
	December 10, 2020	6,420	5,885	€145.5045	December 10, 2030

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 ten 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 II") who were elected at the annual general meeting held in 2020 for a term expiring at the annual general meeting to be held 2022; and a second class of directors ("Class I") who were elected at the annual general meeting held in 2019 for a term expiring at the annual general meeting to be held in 2021. 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. Wolff 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. Directors, Senior Management and Employees—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 judgement 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(b) 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 "Item 6A. Directors, Senior Management and Employees—Directors and Senior Management."

D. Employees

The following tables specify full-time employees at the end of period, per their main activity function and geographic location for the past three financial years.

	Selling, General and Administration (1)	Research and Development	Total
December 31, 2020			
Denmark (Domicile country)	50	167	217
Germany	—	96	96
United States	63	106	169
Total	**113**	**369**	**482**

Of full-time employees, 169 (35.1%) hold a Ph.D., M.D., and/or equivalent degrees.

	Selling, General and Administration (1)	Research and Development	Total
December 31, 2019			
Denmark (Domicile country)	35	121	156
Germany	—	73	73
United States	33	68	101
Total	**68**	**262**	**330**

Of full-time employees, 121 (36.7%) hold a Ph.D., M.D., and/or equivalent degrees.

	Selling, General and Administration (1)	Research and Development	Total
December 31, 2018			
Denmark (Domicile country)	23	78	101
Germany	—	60	60
United States	15	40	55
Total	**38**	**178**	**216**

Of full-time employees, 76 (35.1%) holds a Ph.D., M.D., and/or equivalent degrees.

(1) Selling, General and Administration function includes business and corporate development, and pre-commercial activities.

Number of full-time employees has increased, primarily due to pre-commercial activities, and extension of corporate functions to support those activities. In addition, employees engaged with research and development have increased due to the development of the second therapeutic area, Oncology, which was established in January 2019.

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. Directors, Senior Management and Employees—Compensation—Warrant Incentive Program."

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, 2021, 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, 2021, 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 53,750,386 ordinary shares outstanding as of March 1, 2021. Ordinary shares that a person has the right to subscribe for within 60 days of March 1, 2021 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, 2021, 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
T. Rowe Price Associates, Inc.(1)	6,619,042	—	6,619,042	12.3%
Entities affiliated with RA Capital Management, LLC(2)	5,865,338	—	5,865,338	10.9%
Entities affiliated with Artisan Partners Limited Partnership(3)	5,767,527	—	5,767,527	10.7%
Entities affiliated with FMR LLC(4)	5,341,609	—	5,341,609	9.9%
Baker Bros. Advisors LP(5)	3,540,270	—	3,540,270	6.6%
Entities affiliated with Wellington Management Group LLP(6)	3,401,558	—	3,401,558	6.3%
Entities affiliated with Janus Henderson Group plc(7)	3,008,829	—	3,008,829	5.6%
Senior Management and Board Members				
Jan Møller Mikkelsen(8)	587,096	1,039,756	1,626,852	3.0%
Vibeke Miller Breinholt, Ph.D.(9)	—	24,104	24,104	*
Flemming Steen Jensen(10)	—	81,146	81,146	*
Michael Wolff Jensen, L.L.M.(11)	—	74,646	74,646	*
Sigurd Okkels, Ph.D.(12)	—	37,296	37,296	*
Dana Pizzuti, M.D.(13)	—	11,463	11,463	*
Juha Punnonen, M.D., Ph.D.(14)	—	60,479	60,479	*
Scott T. Smith(15)	—	119,646	119,646	*
Kennett Sprogøe, Ph.D.(16)	30	119,646	119,676	*
Lotte Sønderbjerg(17)	—	122,682	122,682	*
Peter Rasmussen(18)	—	48,987	48,987	*
Lisa Bright(19)	—	37,716	37,716	*
Albert Cha, M.D., Ph.D.(20)	—	84,070	84,070	*
James I. Healy, M.D., Ph.D.(21)	2,090,850	84,070	2,174,920	4.0%
Lars Holtug, M.Sc.(22)	—	27,215	27,215	*
Birgitte Volck, M.D., Ph.D.(23)	230	46,970	47,200	*
Mark Bach, M.D., Ph.D.(24)	—	5,625	5,625	*
Jesper Høiland(25)	—	20,014	20,014	*

* Indicates beneficial ownership of less than 1% of the total outstanding ordinary shares.

(1) Consists of 6,619,042 ordinary shares and ADSs held by T. Rowe Price Associates, Inc. (“Price Associates”) as reported by Amendment No. 3 to Schedule 13G filed on February 16, 2021 by Price Associates. Price Associates, may be deemed to have sole power to vote over 2,164,281 shares and sole power to dispose of 6,619,042 shares. The address of Price Associates is 100 E. Pratt Street, Baltimore, Maryland 21202.

(2) Consists of 5,618,370 ADSs held by RA Capital Healthcare Fund, L.P. (the “RA Fund”) and 246,968 ADSs held in a separately managed account (the “RA Account”) as reported by Amendment No. 10 to Schedule 13G filed with the SEC on February 16, 2021. RA Capital Healthcare Fund GP, LLC is the general partner of the RA Fund. The general partner of RA Capital Management, L.P. (“RA Capital”) is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are the controlling persons. RA Capital serves as investment adviser for the RA Fund and the RA Account and may be deemed a beneficial owner of the shares held by the RA Fund and the RA Account. The RA Fund has delegated to RA Capital the sole power to vote and the sole power to dispose of all securities held in the RA Fund’s portfolio. The RA Fund, RA Capital, Mr. Kolchinsky and Mr. Shah disclaim beneficial ownership of the shares described herein. The address of the RA Fund, the RA Capital, Mr. Kolchinsky and Mr. Shah is c/o RA Capital Management, L.P., 200 Berkeley Street, 18th Floor, Boston, MA 02116.

(3) Consists of an aggregate of 5,767,527 ordinary shares and ADSs beneficially owned, or that may be deemed to be beneficially owned, by Artisan Partners Limited Partnership (“APLP”), Artisan Investments GP LLC (“Artisan Investments”), Artisan Partners Holdings LP (“Artisan Holdings”) and Artisan Partners Asset Management Inc. (“APAM”) as reported by Amendment No. 1 to Schedule 13G filed on February 10, 2021. Artisan Holdings is the sole limited partner of APLP and the sole member of Artisan Investments; Artisan Investments is the general partner of APLP; APAM is the general partner of Artisan Holdings.

(4) Consists of an aggregate of 5,341,609 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. 6 to Schedule 13G filed on December 10, 2020 by FMR LLC. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of 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 LLC (“FMR Co”), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds’ Boards of Trustees. FMR Co 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.

(5) Consists of (i) 3,268,169 ordinary shares and ADSs held by Baker Brothers Life Sciences, L.P. and (ii) 272,101 ordinary shares and ADSs held by 667, L.P. (together with Baker Brothers Life Sciences, L.P., the "Funds") as reported on Amendment No. 3 to Schedule 13G filed on February 14, 2020 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 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 an aggregate of 3,401,558 ordinary shares and ADSs beneficially owned, or that may be deemed to be beneficially owned, by Wellington Management Group LLP ("Management Group"), certain of its affiliates and other companies as reported on Schedule 13G filed on February 3, 2021 by Management Group, Wellington Group Holdings LLP ("Group Holdings"), Wellington Investment Advisors Holdings LLP ("Investment Advisors Holdings"), and Wellington Management Global Holdings, Ltd ("Management Global Holdings", and together with Group Holdings and Investment Advisors Holdings, the "Holding Companies"). Management Group is a parent holding company of the Holding Companies and certain investment advisers listed in the Schedule 13G filed on February 3, 2021(the "Wellington Investment Advisers"). The securities are owned of record by clients of the Wellington Investment Advisors. Investment Advisors Holdings controls directly, or indirectly through Management Global Holdings, the Wellington Investment Advisers. Investment Advisors Holdings is owned by Group Holdings. Group Holdings is owned by Management Group.

(7) Consists of an aggregate of 3,008,829 ordinary shares and ADSs beneficially owned, or that may be deemed to be beneficially owned, by Janus Henderson Group plc ("Janus Henderson") as reported on Schedule 13G filed on February 12, 2021. Janus Henderson has an indirect 97% ownership stake in Intech Investment Management LLC ("Intech") and a 100% ownership stake in Janus Capital Management LLC ("JCM"), Perkins Investment Management LLC ("Perkins"), Henderson Global Investors Limited ("HGIL") and Janus Henderson Investors Australia Institutional Funds Management Limited ("JHIAIFML"), (each an "Asset Manager" and collectively as the "Asset Managers"). Due to the above ownership structure, holdings for the Asset Managers are aggregated for purposes of this filing. Each Asset Manager is an investment adviser registered or authorized in its relevant jurisdiction and each furnishing investment advice to various fund, individual and/or institutional clients (collectively referred to herein as "Managed Portfolios"). As a result of its role as investment adviser or sub-adviser to the Managed Portfolios, JCM may be deemed to be the beneficial owner of 3,008,829 shares or 5.6% of the shares outstanding of Ascendis American Depositary Shares held by such Managed Portfolios. However, JCM does not have the right to receive any dividends from, or the proceeds from the sale of, the securities held in the Managed Portfolios and disclaims any ownership associated with such rights.

(8) Consists of (i) 587,096 ordinary shares held by Mr. Mikkelsen and (ii) 1,039,756 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Mr. Mikkelsen.

(9) Consists of 24,104 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Dr. Breinholt.

(10) Consists of 81,146 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Mr. Jensen.

(11) Consists of 74,646 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Mr. Jensen.

(12) Consists of 37,296 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Dr. Okkels.

(13) Consists of 11,463 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Dr. Pizzuti.

(14) Consists of 60,479 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Dr. Punnonen.

(15) Consists of 119,646 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Mr. Smith.

(16) Consists of (i) 119,646 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Dr. Sprogøe and (ii) 30 ADSs held by family members of Dr. Sprogøe.

(17) Consists of 122,682 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Ms. Sønderbjerg.

(18) Consists of 48,987 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Mr. Rasmussen.

(19) Consists of 37,716 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Ms. Bright.

(20) Consists of 84,070 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Dr. Cha.

(21) Consists of (i) 84,070 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Dr. Healy, (ii) 2,080,800 ordinary shares and ADSs held by Sofinnova Venture Partners IX, L.P. ("SVP IX") and (iii) 10,050 ordinary shares and ADSs held by Sofinnova Management IX, L.L.C. ("SM IX"). SM IX is the general partner of SVP IX and 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 Michael Powell, the managing members of SM IX, may be deemed to have shared voting and dispositive power over the shares directly owned by each of SVP IX and SM IX. Each of Dr. Healy and Mr. Powell disclaim beneficial ownership over the shares held by SVP IX and SM IX, except to the extent of their pecuniary interests therein. The address of SVP IX is c/o Sofinnova Ventures, Inc., 3000 Sand Hill Road, Bldg. 4, Suite 250, Menlo Park, California 94025.

(22) Consists of 27,215 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Mr. Holtug.
(23) Consists of (i) 46,970 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Dr. Volck and (ii) 230 ADSs held by family members of Dr. Volck.
(24) Consists of 5,625 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Dr. Bach.
(25) Consists of 20,014 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2021 by Mr. Høiland.

Record holders

As of March 1, 2021, assuming that all of our ordinary shares represented by ADSs are held by residents of the United States, 100% of our outstanding ordinary shares were held in the United States by three holders of record and none of our outstanding ordinary shares were held outside of the United States. At such date, there were outstanding 52,184,314 ADSs, each representing one of our ordinary shares, and in the aggregate representing 97.1% 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, 2020 with any of our board members, our senior management, the owners of more than five percent of our share capital, and any other related parties.

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

On January 8, 2021, we announced the completion of a Series B financing by VISEN Pharmaceuticals, or VISEN, a company established in 2018 to develop, manufacture and commercialize innovative endocrinology therapies in the People’s Republic of China, including Hong Kong, Macau, and Taiwan, or Greater China. VISEN raised approximately $150 million in gross proceeds from certain investors in this financing, including $12.5 million from us.

In connection with the Company’s investment in VISEN, on January 8, 2021, we entered into an Amended and Restated Shareholders Agreement, amending and restating the Shareholders Agreement dated November 7, 2018, between us and the parties set forth therein.

We have provided research and development services to VISEN under our Rights Agreements which will be reimbursed by VISEN. Further, we have provided product supply to VISEN under our clinical supply agreement for use in conducting clinical trials in Greater China.

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 24 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 4,140,846 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 28, 2024.
- Our board of directors is authorized to increase our share capital by up to 9,000,000 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 May 28, 2024.
- Our board of directors is authorized to issue 682,509 warrants and to increase our share capital by up to 682,509 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. This authorization is valid until May 28, 2025.
- 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 9,000,000 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 May 28, 2024.
- 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 77,073,741 shares consisting of 77,073,741 shares with a nominal value of DKK 1 each.

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 when thresholds of 10%, 15%, 20%, 25%, 50%, 90% or 100%, or 1/3 or 2/3 are reached or no longer reached.

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 ten 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 2019 for a term expiring at the annual general meeting to be held in 2021; and a second class of directors ("Class II") who were elected at the annual general meeting held in 2020 for a term expiring at the annual general meeting to be held in 2022. 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, 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 10%, 15%, 20%, 25%, 50%, 90% or 100%, or 1/3 or 2/3 are reached or 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.

Pursuant to section 58a, we are 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 who ultimately holds or controls, directly or indirectly, a sufficient part of the ownership interests or voting rights or exercises control by other means, except for owners of companies whose ownership interests are traded on a regulated market or a similar market which is subject to a duty of disclosure in accordance with EU law or similar international standards.

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, which will in case of the annual general meeting include the annual report, 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, loss, 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 judgement in the performance of their duties. Informed business judgement 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 twelve 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)

In 2021, gains from the sale of shares are taxed as share income at a rate of 27% on the first DKK 56,500 (for cohabiting spouses, a total of DKK 113,000) and at a rate of 42% on share income exceeding DKK 56,500 (for cohabiting spouses over DKK 113,000). 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 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 two months or the excess tax will offset the corporation income tax for the year. The statute of limitation is three years.

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, the alternative minimum tax, 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 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 or pass-through entities 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 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, or other entity taxable as 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 under U.S. Treasury Regulations 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, 2020. 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 (generally 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, regardless of whether we continue to meet the income or asset tests described above, 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 your holding period 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 income 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 are listed 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

Distributions 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 deposit 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 100ADSs)	• 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 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, 2020, 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, 2020. 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, 2020.

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, 2020, which is included under "Item 15 C. Control and Procedures—Attestation Report of the Registered Public Accounting Firm", below.

C. Attestation Report of the Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2020 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(b) 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, 2020		Year ended December 31, 2019	
	EUR'000	%	EUR'000	%
Audit Fees	599	83	700	99
Tax Fees	104	14	7	1
All Other Fees	22	3	—	—
Total	**725**	**100**	**707**	**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.

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. Directors, Senior Management and Employees—Board Practices", 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

	Page
Reports of Independent Registered Public Accounting Firm	F-2
Consolidated Statements of Profit or Loss and Other Comprehensive Income for the Years Ended December 31, 2020, 2019 and 2018	F-6
Consolidated Statements of Financial Position as of December 31, 2020 and 2019	F-7
Consolidated Statements of Changes in Equity at December 31, 2020, 2019 and 2018	F-8
Consolidated Cash Flow Statements for the Years Ended December 31, 2020, 2019 and 2018	F-9
Notes to the Consolidated Financial Statements	F-10

Deloitte.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors 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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 March 10, 2021, 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Prepayments, Trade Payables and Accrued Expenses - Clinical Trial Accruals — Refer to Notes 2 and 3 to the financial statements

Critical Audit Matter Description

The Company recognises the costs that it incurs for clinical trial activities as research and development expenses based on its evaluation of its vendors' progress toward completion of specific tasks. Payment timing may differ significantly from the period in which the costs are recognised as expense, resulting in clinical trial accruals or prepaid expenses recognised within Prepayments or Trade Payables and Accrued Expenses in the Statement of Financial Position.

In estimating the vendors' progress toward completion of specific tasks, the Company uses data such as patient enrolment, clinical site activations or vendor information of actual costs incurred. This data is obtained through reports from or discussions with Company personnel and outside service providers as to the progress or state of completion of trials, or the completion of services. Costs that are paid in advance are deferred as a prepaid expense and amortised over the service period as the services are provided. Costs for services provided but have not yet been paid are recognised as accruals.

We identified clinical trial accruals as a critical audit matter due to the number of ongoing clinical trial activities, the subjectivity involved in estimating clinical trial accruals, and because auditing the clinical trial accruals involves judgement in assessing the progress of the research and development activities relative to the costs incurred.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to clinical trial accruals included the following, among others:

- We tested the effectiveness of controls over clinical trial accruals;
- We obtained and read selected contract research organisation and contract manufacturing organisation agreements, as well as amendments thereto;
- We evaluated publicly available information (such as press releases and investor presentations) and Board of Directors' materials regarding the status of clinical trial activities and compared this information to the judgements applied in recording the accruals and prepaid expenses;
- For a selection of contracts, we compared the amount of accrual or prepaid expenses at the end of the prior period to current year activity and evaluated the appropriateness of the Company's estimation methodology;
- For a selection of open purchase orders, we assessed management's judgements and estimates in determining whether an accrual should be recorded; and
- We made selections of specific amounts recognised as research and development expense as well as those recognised as accrued and prepaid expenses and performed the following procedures:
    - Assessed management's estimate of the vendor's progress with Company clinical operations personnel;
    - Obtained the related statement of work, purchase order, or other supporting documentation (such as communications between the Company and vendors) and evaluated management's judgments compared to the evidence obtained; and
    - Obtained the listing of all contracts related to research and development expenses to evaluate the completeness of accruals and prepaid expenses.

Deloitte Statsautoriseret Revisionspartnerselskab
CVR no. 33963556

/s/ Sumit Sudan
State Authorised Public Accountant

/s/ Lars Hansen
State Authorised Public Accountant

Copenhagen, Denmark

March 10, 2021

We have served as the Company's auditor since 2007.

Deloitte.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and Board of Directors 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, 2020, 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, 2020, 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, 2020, of the Company and our report dated March 10, 2021, 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.

Deloitte Statsautoriseret Revisionspartnerselskab
CVR no. 33963556

/s/ Sumit Sudan
State Authorised Public Accountant

/s/ Lars Hansen
State Authorised Public Accountant

Copenhagen, Denmark

March 10, 2021

Consolidated Statements of Profit or Loss and Other Comprehensive Income for the Years Ended December 31

	Notes	2020	2019	2018
			(EUR'000)	
Consolidated Statement of Profit or Loss				
Revenue	**4**	6,953	13,375	10,581
Research and development costs	**6**	(260,904)	(191,621)	(140,281)
Selling, general and administrative expenses		(76,669)	(48,473)	(25,057)
Operating profit/(loss)		**(330,620)**	**(226,719)**	**(154,757)**
Share of profit/(loss) of associate	**13**	(9,524)	(8,113)	(321)
Finance income	**9**	1,812	17,803	24,714
Finance expenses	**9**	(80,842)	(1,221)	(127)
Profit/(loss) before tax		**(419,174)**	**(218,250)**	**(130,491)**
Tax on profit/(loss) for the year	**10**	219	234	394
Net profit/(loss) for the year		**(418,955)**	**(218,016)**	**(130,097)**
Attributable to owners of the Company		**(418,955)**	**(218,016)**	**(130,097)**
Basic and diluted earnings/(loss) per share		€(8.28)	€(4.69)	€(3.17)
Number of shares used for calculation (basic and diluted) (1)		50,616,528	46,506,862	41,085,237
			(EUR'000)	
Consolidated Statement of Comprehensive Income				
Net profit/(loss) for the year		**(418,955)**	**(218,016)**	**(130,097)**
Other comprehensive income/(loss)				
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translating foreign operations		(42)	(37)	17
Other comprehensive income/(loss) for the year, net of tax		**(42)**	**(37)**	**17**
Total comprehensive income/(loss) for the year, net of tax		**(418,997)**	**(218,053)**	**(130,080)**
Attributable to owners of the Company		**(418,997)**	**(218,053)**	**(130,080)**

(1) A total of 6,148,004 warrants outstanding as of December 31, 2020 (a total of 5,820,211 warrants and 5,611,629 warrants outstanding as of December 31, 2019 and 2018, 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	2020	2019
		(EUR'000)	
Assets			
Non-current assets			
Intangible assets	**11**	5,717	3,495
Property, plant and equipment	**12**	108,112	45,069
Investment in associate	**13**	9,176	15,538
Other receivables	**14, 20**	1,375	1,463
Marketable securities	**20**	115,280	—
		239,660	**65,565**
Current assets			
Trade receivables	**20**	387	804
Other receivables	**14, 20**	6,957	4,609
Prepayments		13,994	7,648
Marketable securities	**20**	134,278	—
Cash and cash equivalents	**20**	584,517	598,106
		740,133	**611,167**
Total assets		**979,793**	**676,732**
Equity and liabilities			
Equity			
Share capital	**15**	7,217	6,443
Distributable equity	**16**	831,494	590,671
Total equity		**838,711**	**597,114**
Non-current liabilities			
Lease liabilities	**17**	85,116	30,720
Other liabilities		3,162	908
		88,278	**31,628**
Current liabilities			
Lease liabilities	**17**	6,859	5,899
Contract liabilities	**18**	363	858
Trade payables and accrued expenses	**20**	21,897	27,765
Other liabilities		23,384	13,349
Income taxes payable		301	119
		52,804	**47,990**
Total liabilities		**141,082**	**79,618**
Total equity and liabilities		**979,793**	**676,732**

Consolidated Statements of Changes in Equity

	Distributable Equity				
	Share Capital	Share Premium	Foreign Currency Translation Reserve	Share-based Payment Reserve	Accumulated Deficit	Total
	(EUR '000)					
Equity at January 1, 2018	**4,967**	**422,675**	**(14)**	**22,793**	**(263,210)**	**187,211**
Loss for the year	—	—	—	—	(130,097)	**(130,097)**
Other comprehensive income/(loss), net of tax	—	—	17	—	—	**17**
Total comprehensive income/(loss)	**—**	—	**17**	**—**	**(130,097)**	**(130,080)**
Transactions with Owners						
Share-based payment (Note 7)	—	—	—	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**
Loss for the year	—	—	—	—	(218,016)	**(218,016)**
Other comprehensive income/(loss), net of tax	—	—	(37)	—	—	**(37)**
Total comprehensive income/(loss)	**—**	—	**(37)**	**—**	**(218,016)**	**(218,053)**
Transactions with Owners						
Share-based payment (Note 7)	—	—	—	37,486	—	**37,486**
Capital increase	784	528,548	—	—	—	**529,332**
Cost of capital increase	—	(31,701)	—	—	—	**(31,701)**
Equity at December 31, 2019	**6,443**	**1,122,097**	**(34)**	**79,931**	**(611,323)**	**597,114**
Loss for the year	—	—	—	—	(418,955)	**(418,955)**
Other comprehensive income/(loss), net of tax	—	—	(42)	—	—	**(42)**
Total comprehensive income/(loss)	**—**	—	**(42)**	**—**	**(418,955)**	**(418,997)**
Transactions with Owners						
Share-based payment (Note 7)	—	—	—	53,170	—	**53,170**
Capital increase	774	638,023	—	—	—	**638,797**
Cost of capital increase	—	(31,373)	—	—	—	**(31,373)**
Equity at December 31, 2020	**7,217**	**1,728,747**	**(76)**	**133,101**	**(1,030,278)**	**838,711**

Consolidated Cash Flow Statements for the year Ended December 31

	2020	2019	2018
		(EUR'000)	
Operating activities			
Net profit/(loss) for the year	**(418,955)**	**(218,016)**	**(130,097)**
Reversal of finance income	(1,812)	(17,803)	(24,714)
Reversal of finance expenses	80,842	1,221	127
Reversal of tax charge	(219)	(234)	(394)
Adjustments for non-cash items:			
Non-cash consideration regarding revenue	(3,499)	(6,522)	(10,508)
Share of profit/(loss) of associate	9,524	8,113	321
Share-based payment	53,170	37,486	19,652
Depreciation	9,448	6,689	880
Changes in working capital:			
Receivables	(1,996)	(2,182)	(1,048)
Prepayments	(6,357)	4,766	(5,508)
Contract liabilities (deferred income)	(495)	(6,044)	—
Trade payables, accrued expenses and other payables	7,884	7,530	8,262
Cash flows generated from/(used in) operations	**(272,465)**	**(184,996)**	**(143,027)**
Finance income received	1,326	10,056	4,020
Finance expenses paid	(1,504)	(717)	(127)
Income taxes received/(paid)	1,095	(279)	332
Cash flows from/(used in) operating activities	**(271,548)**	**(175,936)**	**(138,802)**
Investing activities			
Acquisition of property, plant and equipment	(19,860)	(5,159)	(2,648)
Reimbursement from acquisition of property, plant and equipment	5,054	—	—
Development expenditures (software)	(1,692)	—	—
Purchase of marketable securities	(537,752)	—	—
Settlement of marketable securities	263,051	—	—
Cash flows from/(used in) investing activities	**(291,199)**	**(5,159)**	**(2,648)**
Financing activities			
Payment of lease liabilities (principal amount)	(4,774)	(4,038)	—
Capital increase	638,797	529,332	216,385
Cost of capital increase	(31,373)	(31,701)	(13,118)
Cash flows from/(used in) financing activities	**602,650**	**493,593**	**203,267**
Increase/(decrease) in cash and cash equivalents	**39,903**	**312,498**	**61,817**
Cash and cash equivalents at January 1	598,106	277,862	195,351
Effect of exchange rate changes on balances held in foreign currencies	(53,492)	7,746	20,694
Cash and cash equivalents at December 31	**584,517**	**598,106**	**277,862**
Cash and cash equivalents include:			
Bank deposits	581,872	598,106	277,862
Short-term marketable securities	2,645	—	—
Cash and cash equivalents at December 31	**584,517**	**598,106**	**277,862**

Note 1—General Information

Ascendis Pharma A/S, together with its subsidiaries, is applying its innovative TransCon technologies to build a leading, fully integrated biopharmaceutical 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 March 10, 2021.

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. Significant accounting judgements and estimates used when exercising the accounting policies are described in Note 3.

These 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

Several amendments to and interpretations of IFRS applied for the first time in 2020, which has not had an impact on the accounting policies applied by the Company. Thus, the accounting policies applied when preparing these consolidated financial statements have been applied consistently to all the periods presented, unless otherwise stated.

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, the Company continues to adopt the going concern basis of accounting in preparing the consolidated financial statements.

Basis of Consolidation

The consolidated financial statements include the parent company, Ascendis Pharma A/S, and all enterprises over which the parent company has control. Control of an enterprise exists when the Company has exposure, or rights to, variable returns from its involvement with the enterprise and has the ability to control those returns through its power over the enterprise. Accordingly, the consolidated financial statements include Ascendis Pharma A/S and the subsidiaries listed in Note 23.

Consolidation Principles

The consolidated financial statements comprise the parent company and its subsidiaries at December 31, 2020. Subsidiaries, which are enterprises the Company control at the reporting date, are fully consolidated from the date upon which control is transferred to the Company. They are deconsolidated from the date control ceases.

Control over an enterprise is reassessed 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 Company's voting rights and potential voting rights; and

- Rights arising from other contractual arrangements.

All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between group enterprises are eliminated in full on consolidation.

Subsidiaries and associates 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.

Investment in Associates

An associate is an entity over which the Company has significant influence over financial and operational decisions but without having control or 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 or establishment date.

The consolidated statements of profit or loss include the Company's share of result after tax and other interests of the associate. Transactions between the associate and the Company are eliminated proportionally according to the Company's interest in the associate. Unrealized gains and losses resulting from transactions between the Company and its associate is eliminated to the extent of the Company's interest in the associate.

On each reporting date, the Company determines whether there is objective evidence that the associate is impaired. If there is such evidence, the amount of impairment is calculated 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 Euros, or 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 reporting date are translated using the exchange rate in effect at the reporting 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 reporting date, are recognized in profit or loss as finance income or finance 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 as of the dates of the initial transactions.

Currency Translation of Group Enterprises

When subsidiaries or associates present their financial statements in a functional currency other than EUR, their statements of profit or loss are translated at average exchange rates. Balance sheet items are translated using the exchange rates at the reporting date. Exchange rate differences arising from translation of foreign entities' balance sheet items at the beginning of the year to the reporting date exchange rates as well as from translation of statements of profit or loss from average rates to the exchange rates at the reporting 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 the Company obtains control over the enterprise.

When acquiring new enterprises over which the Company obtains control, the acquisition method is applied. Under this method, assets, liabilities and contingent liabilities of these enterprises are identified and measured at fair value as of 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 an annual impairment test. Impairment is calculated as the difference between the recoverable amount of the cash-generating unit that the goodwill relates to, and its carrying amount. Any impairment loss is recognized in the consolidated statement of profit or loss in a separate line item.

Revenue

Revenue is primarily generated from collaboration and license agreements. Furthermore, revenue is generated from development services under development and commercialization agreements, including delivery of clinical supply material. Additionally, revenue is generated from feasibility studies for potential partners to evaluate if TransCon technologies enable 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 the Company performs.

When contracts with customers are entered into, the goods and/or services promised in the contract are assessed to 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 good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct); and
- the entity’s promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good 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, those goods or services are combined with other promised goods or services until a bundle of goods or services that is distinct is identified.

The transaction price in the contract is measured at fair value and reflects the consideration the Company expects 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, depending on the specific terms and conditions in the contracts.

Revenue is stated net of value added tax and duties collected on behalf of a third party, and discounts. Usually, the payment terms are within one to two months. No payment terms exceed twelve months, and thus transaction prices are not adjusted for financing components.

Research and Development Costs

Research and development costs consist primarily of manufacturing costs, preclinical and clinical study costs performed by Clinical Research Organizations, or CROs, and Contract Manufacturing Organizations, or CMOs, salaries and other personnel costs including pension and share-based payment, the cost of facilities, the cost of obtaining and maintaining the Company's intellectual property portfolio, and depreciation of non-current 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 include a variety of preclinical research activities in order to assess potential drug candidates in non-human subjects, prior to filing an Investigational New Drug Application, or IND, or equivalent. Research costs are recognized in the consolidated statement of profit or loss when incurred.

Development activities relate to activities following an IND or equivalent, and typically 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. Development activities comprise drug candidates undergoing clinical trials starting in phase I (first time drug is administrated in a small group of humans), and further into Phase II and III, which include administration of drugs in large patient groups. Following, and depending on clinical trial results, a Biologic License Application, or BLA, may be submitted to the authorities, to apply for marketing approval, which, with a positive outcome will permit the Company to market and sell the drug products. Long-term extension trials may be ongoing following submission of a BLA.

A substantial part of development activities is performed by CROs and CMOs, usually through long-term contractual collaborations, and may comprise a variety of service and deliveries, where payment terms not necessarily reflect the stage of completion. In order to recognize development costs on an accrual basis, the Company allocates contractual consideration to project stages, and recognizes development cost according to pre-defined attributes and measurement principles (i.e., number of patients enrolled, achieving project milestones, etc.).

Development costs also include manufacturing costs related to validation batches, or process performance qualification batches on development product candidates, and write-downs on inventories manufactured for late-stage development product candidates prior to marketing approval being obtained (pre-launch inventories).

Due to the risk related to the development of pharmaceutical products, the Company cannot estimate the future economic benefits associated with individual development activities with sufficient certainty until the development activities have 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 when incurred.

Selling, General and Administrative Expenses

Selling, general and administrative expenses comprise salaries and other personnel costs including pension and share-based payment, office supplies, cost of facilities, and depreciation of non-current assets related to general, administrative activities, and pre-commercial activities. Selling, 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 select external consultants have the option to subscribe 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 (i.e., 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 the 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.

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.

Any social security contributions payable in connection with the grant or exercise of the warrants are recognized as expenses when incurred. The assumptions used for estimating the fair value of share-based payment transactions are disclosed in Note 7.

Finance Income and Expenses

Finance income and expenses comprise interest income and expenses, amortization of securities, 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 cash payments or receipts through the expected life of the financial asset or financial liability to the amortized cost (the carrying amount), of such asset or liability.

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 consolidated statement of financial position, 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 reporting 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. In addition, taxable profit or loss 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 profit or loss nor taxable income.

Deferred tax liabilities are recognized on all temporary differences related to investments in subsidiaries and/or associates, unless the Company is 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 assets, including the tax base of tax loss carry forwards, are recognized in the statement of financial position 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. Deferred tax assets are only offset against deferred tax liabilities if the entity has a legally enforceable right to set off, and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same tax jurisdiction. 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 reporting 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. On every reporting date, it is assessed whether sufficient taxable income is likely to arise in the future for the deferred tax asset to be utilized.

Intangible assets

Goodwill

Goodwill acquired in a business combination 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.

Software

Software assets comprise administrative applications and serve general purposes to support operations.

Development costs that are directly attributable to the design, customization, implementation, and testing of identifiable and unique software assets controlled by the Company are recognized as intangible assets from the time that; (1) the software asset is clearly defined and identifiable; (2) technological feasibility, adequate resources to complete, and an internal use of the software asset can be demonstrated; (3) the expenditure attributable to the software asset can be measured reliably; and (4) the Company has the intention to use the software asset internally.

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses. Amortization of the asset begins when the development is complete, and the asset is available for use. Software assets are amortized over the period of expected future benefits. Amortization is recognized in research and development costs, and selling, general and administrative expenses, as appropriate. During the period of development, the asset is tested for impairment, at least annually, or if there are indications that a software asset is impaired. Expenditures, that do not meet the criteria above are recognized as an expense as incurred. The Company does not capitalize software with no alternative use, or where economic benefit depends on marketing approvals of drug candidates and where marketing approvals have not been obtained.

Property, Plant and Equipment

Property, plant and equipment primarily comprises leasehold improvements, office facilities, and process equipment and tools which are located at CMOs.

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 used in operation. Property, plant and equipment also includes right-of-use assets. Please refer to the section “Leases”. 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 the Company 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 with alternative use, which is expected to be used for more than one year, is capitalized and depreciated over the estimated useful life as research and development costs. Plant and equipment acquired for research and development activities, which has no alternative use, is recognized as research and development costs when incurred.

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. Cost of a combined asset is divided into smaller components, with such significant 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 intended.

Depreciation is calculated on a straight-line basis, based on an asset's expected useful life, being within the following ranges:

Process plant and machinery	5 - 10 years
Other fixtures and fittings, tools and equipment	3 - 5 years
Leasehold improvements	3 - 11 years
Right-of-use assets	2 - 11 years

Depreciation methods, useful lives and residual amounts are reassessed at least annually.

Property, plant and equipment is written down to the lower of recoverable amount and carrying amount, as described in the "Impairment" section below. Depreciation and impairment losses of property, plant and equipment is recognized in the consolidated statement of profit or loss as research and development costs or as selling, general and administrative expenses, as appropriate.

Gains and losses on disposal of property, plant and equipment are recognized in the consolidated statement of profit or loss at its net proceeds, as either other income or other expenses, as appropriate.

Impairment

The recoverable amount of goodwill and development projects in progress (software assets) is estimated annually irrespective of any recorded indications of 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.

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 trade receivables and other receivables, which are separately presented in the consolidated statements of financial position.

Trade 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. Other receivables related to VAT, other indirect tax and income tax are measured at cost less impairment. Deposits are initially measured at their fair value and subsequently measured at amortized cost. The carrying amounts of receivables usually equals their nominal value less provision for impairments.

Prepayments

Prepayments comprise advance payments relating to a future financial period. Prepayments are measured at cost.

Marketable Securities

Marketable securities may comprise government bonds, treasury bills, commercial papers, and other securities traded on established markets. In addition, the Company's investment policy only allows investments in marketable securities having investment grade credit-ratings, as assigned by international credit-rating agencies. Marketable securities are primarily held to mitigate concentration of credit risks on cash deposits and to preserve capital. In addition, liquidity risk is managed by maintaining adequate cash reserves and banking facilities, and by matching the maturity profiles of financial assets (including marketable securities), with cash-forecasts (including payment profiles on liabilities).

At initial recognition (trade-date), contractual terms of individual securities are analyzed to determine whether these give rise on specified dates to cash flows that are solely payments of principal and interest on the principal outstanding. This assessment is referred to as the SPPI-test. All marketable securities held at the reporting date, have passed the SPPI-test.

Marketable securities are initially recognized at fair value at trade-date, and subsequently measured at amortized cost under the effective interest method. Interest income is recognized as finance income in the consolidated statement of profit or loss. Marketable securities are subject to impairment tests to accommodate expected credit loss. Gains and losses are recognized as finance income or expenses in the consolidated statement of profit or loss when the specific security or portfolio of securities is derecognized, modified or impaired.

Marketable securities, having maturity profiles of three months or less after the date of acquisition are presented as cash equivalents in the consolidated statements of financial position, where securities having maturities of more than three months after the date of acquisition are presented separately as marketable securities as current (i.e., those maturing within twelve months after the reporting date) or non-current assets, as appropriate.

Cash and Cash Equivalents

Cash and cash equivalents comprise cash and on-demand deposits with financial institutions, and highly liquid marketable securities with a maturity of three months or less after the date of acquisition (trade-date). 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, other indirect tax and income tax), marketable securities and cash and cash equivalents. Provision for bad debts is determined on the basis of a forward-looking Expected Credit Loss, or ECL model. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and the cash flows expected to be received, discounted by an approximation of the original effective interest rate.

For receivables, we apply a simplified approach in calculating ECLs. Therefore, we do not track changes in credit risk, but instead we assess a loss allowance based on lifetime ECL at each reporting date. Lifetime ECLs are assessed on historical credit loss experience, adjusted for forward-looking factors specific to the counterparts and the economic environment.

For cash, cash equivalents and marketable securities, ECLs are assessed for credit losses that result from default events that are possible within the next twelve months, or 12-month ECL. Marketable securities have investment grade ratings, and thus, the risk from probability of default is low. Accordingly, at initial recognition, 12-month ECL is the same as lifetime ECL. Credit risk is continuously tracked and monitored in order to identify significant deterioration. For those credit exposures for which there have been a significant increase in credit risk since initial recognition, an allowance is recognized for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default.

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 foreign operations from their functional currencies to the presentation currency. The accumulated reserve of a foreign

operation is recognized in the consolidated statement of profit or loss at the time the Company loses 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 warrant programs. The share-based payments reserve is an unrestricted reserve that is available to be distributed as dividends to the Company's shareholders.

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

On January 1, 2019, the Company adopted IFRS 16, "Leases", or IFRS 16. Thus, until December 31, 2018, leases of property, plant and equipment, where the Company had substantially all of the risks and rewards of ownership, were classified as finance leases. Other leases were classified as operating leases. Since no finance leases were in place at December 31, 2018 or December 31, 2017, all leases were classified as operating leases, and accordingly, all lease payments were recognized on a straight-line basis in the consolidated statement of profit or loss over the lease term. IFRS 16 was implemented by applying the modified retrospective approach. Accordingly, no comparative information was restated. The lease liability and corresponding right-of-use assets was measured at the present value of the remaining lease payments, discounted using an estimated incremental borrowing rate at January 1, 2019.

From January 1, 2019, contracts are assessed at inception date to identify whether they contain a lease, i.e., if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Except for short-term leases and leases of low value assets, the Company applies a single recognition and measurement approach as described below. For short-term leases and leases of low value assets, lease payments are recognized on a straight-line basis over the lease term in the consolidated statement of profit or loss as research and development costs or as selling, general and administrative expenses, as appropriate. The Company does not act as a lessor, neither does it act as a sub-lessor.

Right-of-use Assets

Right-of-use assets are recognized at the lease commencement date, defined as the date the underlying asset is available for use. Right-of-use assets are measured at cost, less any accumulated depreciations and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets include the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any incentives received. In addition, right-of-use assets also include an estimate of costs to be incurred by the Company in dismantling or restoring the underlying asset to the condition required by the terms and condition of the lease.

Right-of-use assets are presented as part of property, plant and equipment, and depreciated on a straight-line basis over the shorter of the lease term and the estimated useful lives of the assets.

Lease Liabilities

At the lease commencement date, lease liabilities are recognized and measured at the present value of fixed lease payments and variable lease payments that depend on an index or a rate, whereas variable lease payments and payments related to non-lease components are excluded. Variable lease payments that do not depend on an index or a rate are recognized as expenses in the consolidated statement of profit or loss when incurred.

When interest rates implicit in the lease contracts are not readily available, the present value of lease payments are calculated by applying the incremental borrowing rate of the relevant entity holding the lease. Following the commencement date, the incremental borrowing rate is not changed unless the lease term is modified, or if the lease payments are modified and this modification results from a change in floating interest rates. From the lease commencement date and over the lease term, the carrying amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in lease term, or a change in lease payments, including changes to future payments resulting from a change in an index used to determine such lease payments.

Trade Payables and Accrued Expenses

Trade payables and accrued expenses are measured at amortized cost.

Other Liabilities

Other liabilities comprise payables to public authorities, and short-term employee benefits. Other liabilities are measured at their net-realizable values.

Contract Liabilities

Contract liabilities comprise deferred income from collaboration agreements and license agreements, where consideration received does not match the individual deliverables with respect to amount and satisfied performance obligations. Deferred income typically arises from up-front payments under collaboration and license agreements, relating to license grants or up-front funding of development activities.

Deferred income is measured at the fair value of the consideration received and is recognized as revenue in the consolidated statement of profit or loss when the relevant performance obligation, to which the deferred income 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 finance income, finance expenses and income taxes paid.

Cash flows from investing activities include payments in connection with acquisitions, development, improvement and sale, etc., of intangible assets, property, plant and equipment, and group enterprises. In addition, investing activities include acquisition and settlement of marketable securities.

Cash flows from financing activities comprise payments related to lease liabilities, and 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 and on-demand deposits with financial institutions, and highly liquid marketable securities with a maturity of three months or less after the date of acquisition (trade-date).

Segment Reporting

The Company is 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, no segment information on business segments or geographical markets is disclosed.

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. The consolidated financial statements are not expected to be affected by such new or improved standards.

Note 3 – Significant Accounting Judgements, Estimates and Assumptions

In the application of the Company's accounting policies, management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. Judgements and estimates applied are based on historical experience and other factors that are relevant, and which are available at the reporting date. Uncertainty concerning judgements and estimates could result in outcomes, that require a material adjustment to assets and liabilities in future periods.

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. While the application of critical accounting estimates is subject to material estimation uncertainties, management's ongoing revisions of critical accounting estimates have not revealed any material impact in any of the years ended December 31, 2020, 2019 or 2018.

Critical accounting judgements and key sources of estimation uncertainty, which may have a material impact on the consolidated financial statements are described in following sections.

Revenue

Revenue is primarily generated from collaboration and license agreements, which typically involve multiple promises, and thus require significant judgements by management 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 judgements relating to specific revenue transactions are described below.

Identifying Performance Obligations and Allocating Transaction Price

Three license agreements with the Company's associate VISEN, or licensee, grant the licensee exclusive rights to develop, manufacture, and commercialize patented product candidates in Greater China, including the right to grant sub-licenses to third parties. In addition to the licenses, the Company will provide development services and deliver clinical supply material for clinical trials within Greater China.

In determination of the performance obligations under the license agreements, the stand-alone values of the promises and the Company's responsibility in the development activities have been considered. Since licensed product candidates are all in phase 1 clinical trials or later stages of development, the licensee can benefit from each promise in the contract either on their own or together with readily available resources. Accordingly, licenses, development services, and clinical trial supplies are all considered distinct performance obligations.

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

Management has considered whether the Company is obligated or expected to perform research and development activities that significantly affect the licensee's ability to benefit from product candidates. If the Company is contractually obligated, or is 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". Since licensed products are patented drug formulas, future activities do not affect their stand-alone functionalities. Accordingly, all three licenses 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 consolidated statement of profit or loss and financial position, the effects of share-based payment transactions. Warrant compensation costs are recognized as research and development costs or selling, general and administrative expenses, as appropriate, over the vesting period, based on management’s best estimate of the number of warrants that will ultimately vests, which is subject to uncertainty. In addition, warrant compensation costs are measured according to the grant date fair values of the warrants granted. Estimating fair values requires the Company to apply generally accepted valuation models, and apply these models consistently according to the terms and conditions of the specific warrant program. Under all warrant programs, the Black-Scholes option-pricing model has been applied to determine the fair value of warrants granted. Subjective judgements and assumptions, which are subject to estimation uncertainties, need to be exercised in determining the appropriate input to the valuation model.

See Note 7 for additional details on the Company’s warrant programs, option-pricing model input. Warrant compensation cost recognized in the consolidated statement of profit or loss was €53.2 million, €37.5 million and €19.7 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Internally Generated Intangible Assets

Development of Drug Candidates

IAS 38, “Intangible Assets” prescribes that intangible assets arising from development projects must be recognized in the consolidated statements of financial position 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 the Company has the intent to produce and market the product. Such an intangible asset shall be recognized if it can be demonstrated 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 related to drug candidates cannot be determined with sufficient certainty until the development activities have been completed and the necessary marketing approvals have been obtained. Accordingly, the Company does not recognize internally generated intangible assets at this time.

Joint Arrangements

Collaboration and license agreements within the Company’s industry are often structured so that each party contributes its respective skills in the various phases of a development project, and significant judgement is required by management to determine whether such agreements comprise customer/supplier relationship or joint arrangements where parties share risks and rewards.

It has been concluded that no joint control exists for the Company’s license agreements and the parties do not have any financial obligations on behalf of each other. Accordingly, since neither of the license agreements are considered to be joint arrangements, these are classified as contracts with customers.

Pre-launch Inventories

In order to accommodate market demands, the Company initiates manufacturing of inventories for late-stage development product candidates prior to obtaining marketing approvals, or pre-launch inventories.

In determining the accounting for pre-launch inventories, management considers the probability of future benefits, and accordingly, whether pre-launch inventories qualify as assets. Manufacturing of pre-launch inventories are initiated for late-stage product candidates and are recognized as inventories. However, since pre-launch inventories are not realizable prior to obtaining marketing approvals, pre-launch inventories are immediately written down to zero through research and development costs. If the marketing approval is obtained, write-downs of pre-launch inventories will be reversed through research and development costs.

Accruals and Prepayments

Project Development Costs

Development of drug candidates requires spend of significant resources, and establishment of long-term working relationships with CROs and CMOs. Work performed by CROs and CMOs and other project suppliers, often comprise deliveries for more than one reporting period, and where payment terms for contractual work do not necessarily reflect the stage of completion of the individual projects and activities. Accordingly, determination of the stage of completion for ongoing project activities include estimation uncertainties as future efforts to complete the specific activity may be difficult to predict.

On each reporting date, all significant ongoing activities are reviewed to determine the stage of completion and compared to the invoices received. Accruals are recognized for individual projects where the stage of completion exceeds costs of invoices received. Similarly, prepayments are recognized for invoiced costs in excess of the stage of completion. The Company has implemented accrual calculation models and policies, to ensure that consistent accrual procedures are applied, which includes analyzing significant project stages and payment structures, comparing project milestones to planned performance, and revisiting prior periods estimates.

As of December 31, 2020, the consolidated statement of financial position included prepaid project costs of €10.5 million and accrued project costs of €17.0 million, compared to €5.8 million and €10.5 million, respectively, as of December 31, 2019.

Leases

Determination of Lease Term

Certain lease arrangements include contractual rights (not obligations) to either extend the lease after the initial term, or not to terminate the lease within the enforceable lease term, i.e., periods where lessor cannot terminate the lease. Those options cover periods in the range from two to ten years in addition to the non-cancellable periods. Significant judgement is required by management to determine whether it is reasonably certain to exercise an extension option, or not to exercise a termination option, upon occurrence of an event of change in circumstances that is within the control of the Company.

Except for the above areas, judgements, estimates and assumptions are not considered to be critical to the consolidated financial statements.

Note 4—Revenue

The Company's revenue is primarily generated from three license agreements, which were entered into in 2018. The licenses grant VISEN Pharmaceuticals, or VISEN, exclusive rights to develop and commercialize TransCon hGH, TransCon PTH and TransCon CNP in Greater China. As consideration for the granting of such rights, the Company has received up-front, non-refundable, non-cash consideration of $40.0 million in form of 50% ownership in VISEN. Consideration received is recognized partly as license revenue, and partly as rendering of services over time. In addition to granting exclusive rights, the Company will provide clinical trial supply and development services to VISEN.

Revenue has been recognized in the consolidated statements of profit or loss with the following amounts:

	2020	2019	2018
		(EUR'000)	
Revenue from external customers			
Revenue from rendering of services (recognized over time)	2,140	9,919	1,215
Sale of clinical supply (recognized at a point in time)	2,206	804	—
"Right-to-use" licenses (recognized at a point in time)	2,607	2,652	9,366
Total revenue (1)	**6,953**	**13,375**	**10,581**
Attributable to			
VISEN Pharmaceuticals (1)	6,880	13,371	10,508
Other collaboration partners	73	4	73
Total revenue	**6,953**	**13,375**	**10,581**
Total revenue specified per geographical location			
North America	2,679	2,652	10,581
China	4,274	10,723	—
Total revenue	**6,953**	**13,375**	**10,581**

(1) "Total revenue" includes recognition of previously deferred revenue/internal profit from associate of €3.5 million and €6.5 million for the years ended December 31, 2020 and 2019, respectively.

Note 5—Segment Information

The Company is 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. Entity wide disclosures regarding revenue are included in Note 4.

The Company's intangible assets and property, plant and equipment located by country are specified below, and defines the Company's non-current segment assets:

	2020	2019
	(EUR'000)	
Non-current segment assets		
Denmark (domicile country)	20,288	15,738
North America	85,476	27,275
Germany	8,065	5,551
Total non-current segment assets	**113,829**	**48,564**
Investment in associate	9,176	15,538
Marketable securities	115,280	—
Other receivables	1,375	1,463
Total non-current assets	**239,660**	**65,565**

Note 6—Research and Development Costs

Research and development costs are specified by their nature in the following table:

	2020	2019	2018
		(EUR'000)	
Research and development costs			
Employee costs	92,468	61,890	34,146
Depreciation	7,311	5,282	827
External costs	161,125	124,449	105,308
Total research and development costs	**260,904**	**191,621**	**140,281**

Note 7—Employee costs

	2020	2019	2018
		(EUR'000)	
Employee costs			
Wages and salaries	77,374	49,142	29,418
Share-based payment	53,170	37,486	19,652
Pensions (defined contribution plans)	943	648	444
Social security costs	5,358	3,613	1,793
Total employee costs	**136,845**	**90,889**	**51,307**
Included in the profit or loss			
Research and development costs	92,468	61,890	34,146
Selling, general and administrative expenses	44,377	28,999	17,161
Total employee costs	**136,845**	**90,889**	**51,307**
Average number of employees	410	274	167

Key Management Personnel includes the Board of Directors and Executive Board and comprises seven and two persons, respectively, for all years presented.

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 within total employee costs are summarized below:

	Board of Directors			Executive Board			Total		
	2020	2019	2018	2020	2019	2018	2020	2019	2018
					(EUR '000)				
Employee cost									
Wages and salaries	250	265	244	2,372	1,815	1,565	2,622	2,080	1,809
Share-based payment	1,913	1,864	1,607	6,359	5,303	3,505	8,272	7,167	5,112
Social security costs	—	—	—	100	94	152	100	94	152
Total employee costs	**2,163**	**2,129**	**1,851**	**8,831**	**7,212**	**5,222**	**10,994**	**9,341**	**7,073**

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 the 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, 2020, 10,864,718 warrants had been granted, of which 19,580 warrants have been cancelled, 4,176,645 warrants have been exercised, 2,168 warrants have expired without being exercised, and 518,321 warrants have been forfeited. As of December 31, 2020, the Board of Directors was authorized to grant up to 762,569 additional warrants to 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 the Company's ordinary shares at the time of grant as determined by the 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 generally vest over 48 months with 1/48 of the warrants vesting per month from the date of grant. However, effective from January 2015, 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 the Company, or (ii) in the event that the Company terminates the employment contract and the warrantholder has given the Company 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 the employment contract is terminated and the warrantholder has not given the Company 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 the Company.

Exercise Periods

Vested warrants may be exercised during certain exercise periods each year. At December 31, 2020, for 403,467 outstanding warrants, granted in the period 2012 to 2014, 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) the interim report (six-month report). For these warrants, the last exercise period is 21 days from and including the day after the publication of the interim report for the first half of 2023. At December 31, 2020, for 52,323 outstanding warrants granted in connection with the Preference D financing, there are four annual exercise periods that continue for 21 days following the day of publication of (i) an interim report (three-month report); (ii) the annual report notification—or if such notification is not published—the annual report; (iii) the interim report (six-month report); and (iv) the interim report (nine-month report). For these warrants, the last exercise period is 21 days following the publication of the interim report (nine-month report) in 2023. At December 31, 2020, for 5,692,214 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 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, a sale or share exchange of more than 50% of the Company's 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 the Company at the time the warrants are exercised. If the consultant's, advisor's or board member's relationship with the Company 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

The following table specifies the 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, 2018	**4,621,154**	**17.62**
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 reporting date	**2,478,770**	**15.81**
Granted during the year	1,300,600	97.01
Exercised during the year (1)	(1,058,722)	16.33
Forfeited during the year	(33,296)	58.49
Expired during the year	—	—
Outstanding at December 31, 2019	**5,820,211**	**46.36**
Vested at the reporting date	**2,705,693**	**24.93**
Granted during the year	1,485,931	137.57
Exercised during the year (1)	(905,395)	30.56
Forfeited during the year	(252,743)	64.99
Expired during the year	—	—
Outstanding at December 31, 2020	**6,148,004**	**69.97**
Vested at the reporting date	**3,044,827**	**37.29**

(1) The weighted average share price (listed in $) at the date of exercise was €128.32, €108.54 and €58.01 for the years ended December 31, 2020, 2019 and 2018, respectively.

The following table specifies the weighted average exercise prices and weighted average remaining contractual life for outstanding warrants at December 31, 2020, per grant year.

	Number of Outstanding Warrants	Weighted Average Exercise Price EUR	Weighted Average Remaining Life (months)
Granted in 2012-2017	2,247,134	20.83	66
Granted in 2018	1,288,400	54.56	94
Granted in 2019	1,143,436	96.98	105
Granted in 2020	1,469,034	137.63	117
Outstanding at December 31, 2020	**6,148,004**	**69.97**	**91**

At December 31, 2020, the exercise prices of outstanding warrants under the Company’s warrant programs range from €6.48 to €145.50 depending on the grant dates. The range of exercise prices for outstanding warrants was €6.48 - €107.14, and €6.48 - €60.23, for the years ended December 31, 2019 and 2018, respectively.

The weighted average remaining life for outstanding warrants was 94 months and 96 months, for the financial years ended December 31, 2019 and 2018, respectively.

Warrant Compensation Costs

Warrant compensation costs are recognized in the consolidated statement of profit or loss over the vesting period of the warrants granted.

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 the estimated market price of the Company's 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 the Company's 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 2020, 2019 and 2018:

	2020	2019	2018
Expected volatility	52 – 55%	52 – 54%	53 – 57%
Risk-free interest rate	(0.93) – (0.32)%	(0.77) – (0.05)%	(0.23) –0.46%
Expected life of warrants (years)	5.05 – 7.10	5.05 – 7.10	5.05 – 7.14
Weighted average exercise price	€137.57	€97.01	€54.43
Fair value of warrants granted in the year	€48.43 – 75.77	€27.24 – 55.64	€17.90 – 31.81

Note 8— Principal Accountant Fees and Services

The following table sets forth, for each of the years indicated, the fees billed by the Company's independent public accountants and the proportion of each of the fees out of the total amount billed by the accountants.

	2020	2019	2018
		(EUR'000)	
Principal accountant fees and services			
Audit fees	599	700	693
Tax fees	104	7	—
All other fees	22	—	62
Total principal accountant fees and services	**725**	**707**	**755**

Note 9—Finance Income and Finance Expenses

	2020	2019	2018
		(EUR'000)	
Finance income			
Interest income	1,812	10,056	4,020
Exchange rate gains	—	7,747	20,694
Total finance income	**1,812**	**17,803**	**24,714**
Finance expenses			
Interest expenses	1,918	1,221	127
Exchange rate losses	78,924	—	—
Total finance expenses	**80,842**	**1,221**	**127**

Interest income and interest expenses relate to financial assets and liabilities measured at amortized cost. Interest expense on lease liabilities are specified in Note 17. Exchange rate losses primarily relate to U.S. Dollar/Euro fluctuations pertaining to the Company's, cash, cash equivalents and marketable securities.

Note 10—Tax on Profit/(Loss) for the Year and Deferred Tax

	2020	2019	2018
		(EUR'000)	
Tax on profit/(loss) for the year:			
Current tax (expense)/income	219	234	394
	219	**234**	**394**
Tax for the year can be explained as follows:			
Profit/(loss) before tax	(419,174)	(218,250)	(130,491)
Tax at the Danish corporation tax rate of 22%	**92,218**	**48,015**	**28,708**
Tax effect of:			
Non-deductible costs	(11,815)	(8,249)	(4,327)
Additional tax deductions	24,564	10,875	4,074
Impact from associate	(1,326)	(1,680)	(2,383)
Other effects including effect of different tax rates	2,673	1,602	143
Deferred tax asset, not recognized	(106,095)	(50,329)	(25,821)
Tax on profit/(loss) for the year	**219**	**234**	**394**
Effective tax rate	**(0.05)%**	**(0.11)%**	**(0.30)%**

	2020	2019	2018
		(EUR'000)	
Specification of Deferred Tax Assets			
Tax deductible losses	227,234	123,234	74,120
Other temporary differences	7,726	5,631	4,416
Deferred tax asset, not recognized	(234,960)	(128,865)	(78,536)
Total Deferred Tax Assets at December 31	**0**	**0**	**0**

No changes to deferred tax have been recognized in the consolidated statement of profit or loss for 2020, 2019 or 2018. Deferred tax assets have not been recognized in the consolidated statements of financial position due to uncertainty relating to future utilization. Deferred tax assets can be carried forward without timing limitations.

The Company had tax losses carried forward of €1,043.8 million and €560.2 million at December 31, 2020 and December 2019, respectively. Tax losses can be carried forward infinitely, where 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, 2020, the jointly taxed Danish entities had a negative taxable income, and accordingly were entitled to a tax refund of approximately €0.7 million for each of the years ended December 31, 2020, 2019 and 2018, respectively. The Company is entitled to additional tax deductions, determined by annual warrants exercised by employees. For the year ended December 31, 2020, the Company was entitled to additional tax deductions of €16.3 million, compared to €10.2 million and €3.5 million for the years ended December 31, 2019 and 2018, respectively. The Company is entitled to future tax deductions, which depends on the timing and amounts of warrant exercises, and accordingly, future additional tax deductions is subject to uncertainties. Please refer to Note 7 regarding descriptions of warrant programs.

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 11—Intangible Assets

	Goodwill	Software	Total
		(EUR'000)	
Cost:			
At January 1, 2019	**3,495**	**—**	**3,495**
Additions	—	—	—
Disposals	—	—	—
Foreign exchange translation	—	—	—
At December 31, 2019	**3,495**	**—**	**3,495**
Additions	—	2,222	2,222
Disposals	—	—	—
Foreign exchange translation	—	—	—
At December 31, 2020	**3,495**	**2,222**	**5,717**
Accumulated amortization and impairments:			
At January 1, 2019	**—**	**—**	**—**
Amortization charge	—	—	—
Impairment charge	—	—	—
Disposals	—	—	—
Foreign exchange translation	—	—	—
At December 31, 2019	**—**	**—**	**—**
Amortization charge	—	—	—
Impairment charge	—	—	—
Disposals	—	—	—
Foreign exchange translation	—	—	—
At December 31, 2020	**—**	**—**	**—**
Carrying amount:			
At December 31, 2019	**3,495**	**—**	**3,495**
At December 31, 2020	**3,495**	**2,222**	**5,717**

Software relates to development activities on Enterprise Resource Planning system and is under development at the reporting date. The system was taken into use at January 1, 2021. Of total additions, €0.5 million and €0 million was unpaid at December 31, 2020 and 2019, respectively.

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, at the reporting date, no internally generated intangible assets from development of pharmaceutical drug candidates have been recognized. Thus, all research and development costs incurred for the years ended December 31, 2020, 2019 and 2018, were recognized in the consolidated statements 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. Ascendis Pharma GmbH was initially a separate technology platform company but is now an integral part of the Company's 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 the Company is considered to represent one cash-generating unit. 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.

The recoverable amount of the cash-generating unit is determined based on an estimation of the Company's fair value less costs of disposal. The fair value of goodwill has been determined after taking into account the market value of the Company's ADSs as of the reporting date. The computation of the market value including an estimation of selling costs, significantly exceeded the carrying amount of the net assets, leaving sufficient value to cover the carrying amount of goodwill. Considering the excess value, no further assumptions are deemed relevant to be applied in determining whether goodwill is impaired.

Note 12—Property, Plant and Equipment

	Plant and Machinery	Other Equipment	Leasehold Improve-ments	Right-of-Use Assets	Total
			(EUR'000)		
Cost:					
At January 1, 2019	**5,645**	**2,595**	**875**	**—**	**9,115**
Adoption of IFRS 16, "Leases"	—	—	—	18,437	18,437
Additions	2,393	1,499	3,418	21,225	28,535
Disposals	—	(154)	(7)	—	(161)
Foreign exchange translation	—	4	2	457	463
At December 31, 2019	**8,038**	**3,944**	**4,288**	**40,119**	**56,389**
Additions	7,169	1,635	4,849	64,582	78,235
Disposals	(296)	(221)	(14)	—	(531)
Foreign exchange translation	(289)	(183)	(588)	(5,135)	(6,195)
At December 31, 2020	**14,622**	**5,175**	**8,535**	**99,566**	**127,898**
Accumulated depreciation:					
At January 1, 2019	**(3,448)**	**(954)**	**(388)**	**—**	**(4,790)**
Depreciation charge	(523)	(758)	(170)	(5,237)	(6,688)
Disposals	—	154	—	—	154
Foreign exchange translation	—	(5)	—	9	4
At December 31, 2019	**(3,971)**	**(1,563)**	**(558)**	**(5,228)**	**(11,320)**
Depreciation charge	(1,030)	(956)	(605)	(6,857)	(9,448)
Disposals	204	191	7	—	402
Foreign exchange translation	16	41	22	501	580
At December 31, 2020	**(4,781)**	**(2,287)**	**(1,134)**	**(11,584)**	**(19,786)**
Carrying amount:					
At December 31, 2019	**4,067**	**2,381**	**3,730**	**34,891**	**45,069**
At December 31, 2020	**9,841**	**2,888**	**7,401**	**87,982**	**108,112**

Assets under construction amounts to €2.3 million and €2.7 million at December 21, 2020 and 2019, respectively. Of total additions, €1.0 million and €2.1 million was unpaid at December 31, 2020 and 2019, respectively.

Depreciation charges are specified below:

	2020	2019	2018
		(EUR'000)	
Depreciation charges			
Research and development costs	7,311	5,282	827
Selling, general and administrative expenses	2,137	1,406	53
Total depreciation charges	**9,448**	**6,688**	**880**

Note 13—Investment in Associate

VISEN Pharmaceuticals, or 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, and as consideration for the granting of such rights has received a 50% ownership of VISEN. The other investors contributed, in aggregate, $40.0 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 development, manufacturing and commercialization of endocrinology rare disease therapies in Greater China. 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 VISEN:

VISEN Pharmaceuticals	
Principal place of business	China
Ownership (at December 31, 2020)	50%

	2020	2019
	(EUR'000)	
Statement of profit or loss		
Profit / (loss) for the year from continuing operations	**(19,049)**	**(16,226)**
Total comprehensive income	**(19,049)**	**(16,226)**
Statement of financial position		
Non-current assets	16,635	23,291
Current assets	20,373	32,446
Total assets	**37,008**	**55,737**
Equity	33,708	53,820
Non-current liabilities	152	250
Current liabilities	3,148	1,667
Total equity and liabilities	**37,008**	**55,737**
Company's share of equity before eliminations	**16,854**	**26,910**
Elimination of internal profit recognized at December 31	*(7,678)*	*(11,372)*
Company's share of equity	**9,176**	**15,538**
Investment in associate at December 31	**9,176**	**15,538**

Revenue from VISEN, recognized in the consolidated statement of profit or loss is disclosed in Note 4. Trade receivable balance with VISEN at December 31, 2020 and 2019 was €0.2 million and €0.8 million, respectively. VISEN requires the Company's consent to distribute dividends and incur indebtedness outside the normal course of business.

On January 8, 2021, the Company entered into an equity investment of $12.5 million as part of VISEN's $150 million Series B financing. Please refer to Note 24 regarding subsequent events.

Note 14—Other Receivables

Other receivables comprise following:

	2020	2019
	(EUR'000)	
Other receivables		
Deposits	1,375	1,463
Income tax receivables	778	1,473
VAT receivables	5,276	2,797
Other receivables	903	339
Total other receivables	**8,332**	**6,072**
Classified based on expected realization		
Non-current assets	1,375	1,463
Current assets	6,957	4,609
Total other receivables	**8,332**	**6,072**

Note 15—Share Capital

The share capital of Ascendis Pharma A/S consists of 53,750,386 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:

	2020	2019	2018	2017	2016
Changes in share capital					
Beginning of year	47,985,837	42,135,448	36,984,292	32,421,121	25,128,242
Increase through cash contribution	5,764,549	5,850,389	5,151,156	4,563,171	7,292,879
End of year	**53,750,386**	**47,985,837**	**42,135,448**	**36,984,292**	**32,421,121**

Note 16—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 the Company's foreign operations and associate from their functional currencies to the Company's 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 the Company's warrant programs 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 warrant programs are provided in Note 7. 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 17—Leases

The Company primarily leases office and laboratory facilities. Lease arrangements contain a range of different terms and conditions and are typically entered into for fixed periods. Generally, the lease terms are between two and eleven years, and in addition, in order to improve flexibility to the Company's operations, may provide the Company with options to extend the lease, or terminate the lease within the enforceable lease term. In the Company's current lease portfolio, extension and termination options range between two to ten years, in addition to the non-cancellable period.

To accommodate the current and future development of the Company, additional leases related to office facilities were entered into in 2020, and included recognition of right-of-use assets of €64.6 million. In December 2020, the Company entered into two office facility leases in Denmark, which commence in the first quarter of 2021. The leases are enforceable until January 2037, and July 2029, respectively, whereas the Company has rights to terminate the leases in January 2027, and July 2026, respectively. In addition, a new lease is expected to commence in 2021, and relates to laboratory facilities in Heidelberg, Germany.

Leases Liabilities and Payments

Development in lease liabilities are specified below:

	Beginning of period	Additions	Accretion of interests	Cash out-flow (2)	Foreign exchange translation (non-cash item)	End of period
			(EUR'000)			
Lease liabilities						
December 31, 2020	36,619	64,582	1,617	(5,990)	(4,853)	91,975
December 31, 2019	17,700(1)	21,240	1,014	(3,870)	535	36,619

(1) Beginning balance, December 31, 2019, includes the impact from implementing IFRS 16.
(2) Total cash outflow, including prepaid leases was €6.0 million and €4.5 million for the years ended December 31, 2020 and 2019, respectively.

The maturity analysis of lease liabilities is disclosed in Note 20 "Financial Risk Management and Financial Instruments" in the section "Liquidity Risk Management".

Expenses Relating to Leases

The following expenses relating to lease activities are recognized in the consolidated statements of profit or loss (IFRS 16 was adopted by applying the modified retrospective approach. Accordingly, no comparative information for 2018 is disclosed):

	2020	2019
	(EUR'000)	
Lease expense		
Depreciation (research and development, Note 12)	4,885	3,943
Depreciation (selling, general and administration, Note 12)	1,972	1,294
Expenses relating to short term leases and leases of low value assets (research and development and selling, general and administration)	470	202
Lease interest (finance expenses, Note 9)	1,617	1,014
Total lease expenses	**8,944**	**6,453**

Note 18—Contract Liabilities

Deferred income was €0.4 million and €0.9 million for the years ended December 31, 2020 and 2019, respectively, and relates to partially satisfied performance obligations regarding feasibility studies and research and development of licensed product candidates. The remaining balance of deferred income is expected to be recognized as revenue in 2021, as services are transferred.

Revenue recognized from deferred income was €1.0 million, €6.1 million and €0.0 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Note 19—Commitments and Contingencies

Contractual commitments for the construction of property, plant and equipment were €15.8 million and €8.5 million for the years ended December 31, 2020 and 2019, respectively. With certain suppliers, the Company has agreed minimum commitments related to the manufacturing of product supply, subject to continuous negotiation and adjustments according to the individual contractual terms and conditions. Delivery of product supply is recognized when the Company obtains control of the goods.

In addition, the Company has entered into short-term leases and leases of low value assets, contracts of various lengths in respect of research and development with Clinical Research Operators, and IT and facility related services. Costs relating to those commitments are recognized as services are received.

We are not aware of any significant legal claims or disputes.

Note 20—Financial Risk Management and Financial Instruments

Financial assets and financial liabilities comprise the following:

	2020	2019
	(EUR'000)	
Financial assets		
Trade receivables	387	804
Other receivables	2,251	1,463
Marketable securities	249,558	—
Cash and cash equivalents	584,517	598,106
Financial assets measured at amortized cost	**836,713**	**600,373**
Financial liabilities		
Lease liabilities	91,975	36,619
Trade payables and accrued expenses	21,897	27,765
Financial liabilities measured at amortized cost	**113,872**	**64,384**

Marketable Securities

Marketable securities are measured at amortized cost, and fair values are determined based on quoted market prices (Level 1 in the fair value hierarchy). The composition of the portfolio and its fair values are specified in the following table (the Company did not hold any marketable securities at December 31, 2019):

	Carrying amount	Fair value
	(EUR'000)	
December 31, 2020		
Marketable securities		
U.S. Treasury bills	46,243	46,245
U.S. Government Bonds	62,088	62,101
Commercial papers	10,583	10,581
Corporate bonds	121,282	121,234
Agency bonds	9,362	9,369
Total marketable securities	**249,558**	**249,530**
Classified based on maturity profiles		
Non-current assets	115,280	115,277
Current assets	134,278	134,253
Total marketable securities	**249,558**	**249,530**
Specified by rate structure		
Fixed rate	175,757	175,732
Floating rate	16,975	16,972
Zero-coupon	56,826	56,826
Total marketable securities	**249,558**	**249,530**
Specified by credit-rating		
AAA- – AA-	93,229	93,240
A+ – A-	99,503	99,464
A-1+	56,826	56,826
Total marketable securities	**249,558**	**249,530**

Capital Management

The Company manages 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 debt and equity balances. The overall strategy in this regard has remained unchanged since 2012.

The Company's capital structure consists only of equity comprising issued capital, reserves and retained earnings/accumulated deficits. Although the Company is not subject to any externally imposed capital requirements, the capital structure is reviewed on an ongoing basis. Since the Company does not hold external debt, such review currently comprises a review of the adequacy of the Company's capital compared to the resources required for carrying out ordinary activities.

Financial Risk Management Objectives

The Company regularly monitors the access to domestic and international financial markets, manages the financial risks relating to its operations, and analyze exposures to risk, including market risk, such as foreign currency risk and interest rate risk, credit risk and liquidity risk.

The Company's financial risk exposure and risk management policies are described in following sections.

Market Risk

The Company's activities expose the group enterprises to the financial risks of changes in foreign currency exchange rates and interest rates. Derivative financial instruments are not applied to manage exposure to such risks.

Foreign Currency Risk Management

The Company is exposed to foreign exchange risks arising from various currency exposures, primarily with respect to the U.S. Dollar, or USD, the British Pound, or GBP, and the Danish Krone, or DKK. Foreign exchange rate risks are unchanged to prior year. The proceeds from the series D financing in November 2014, the IPO in February 2015 and follow-on offerings, the latest being in July 2020, were in USD. The exposure from foreign exchange risks are managed by maintaining cash positions in the currencies in which the majority of future expenses are denominated, and payments are made from those reserves.

Foreign Currency Sensitivity Analysis

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 timeframe. At December 31, 2020, the net carrying amount of monetary assets and liabilities was €702.1 million, where the direct exposure from USD (USD monetary assets and liabilities held by non-USD entities) was €797.9, which primarily related to the proceeds from the follow-on offering completed in July 2020 and marketable securities.

The following table details how a strengthening of the USD and the GBP would impact profit and loss and equity before tax at the reporting date. A similar weakening of the USD and the GBP would have the opposite effect with similar amounts. A positive number indicates an increase in profit or loss and equity before tax, while a negative number indicates the opposite. The sensitivity analysis is deemed representative of the inherent foreign exchange risk associated with the operations.

	Nominal positions	Hypothetical impact on consolidated financial statements: Increase in foreign exchange rate	Profit and loss before tax	Equity before. tax
		(EUR '000)		
December 31, 2020				
USD/EUR	797,927	10%	79,793	79,793
GBP/EUR	1,555	10%	155	155

	Nominal positions	Hypothetical impact on consolidated financial statements: Increase in foreign exchange rate	Profit and loss before tax	Equity before tax
		(EUR '000)		
December 31, 2019				
USD/EUR	477,764	10%	47,776	47,776
GBP/EUR	(858)	10%	(86)	(86)

Interest Rate Risk Management

The Company has no interest-bearing debt to third parties. In addition, since the Company holds no derivatives or financial assets and liabilities measured at fair value, the exposure to interest rate risk primarily relates to the interest rates for cash, cash equivalents and marketable securities. Future interest income from interest-bearing bank deposits and marketable securities may fall short of expectations due to changes in interest rates.

The effects of interest rate fluctuations are not considered a material risk to the Company's financial position. Accordingly, no interest sensitivity analysis has been presented.

Credit Risk Management

The Company has adopted an investment policy with the primary purpose of preserving capital, fulfilling liquidity needs and diversifying the risks associated with cash, cash equivalents and marketable securities. This investment policy establishes minimum ratings for institutions with which the Company holds cash, cash equivalents and marketable securities, as well as rating and concentration limits for marketable securities held.

All material counterparties are considered creditworthy. While the concentration of credit risk may be significant, the credit risk for each individual counterpart is considered to be low. The exposure to credit risk primarily relates to cash, cash equivalents, and marketable securities. The credit risk on bank deposits is limited because the counterparties, holding significant deposits, are banks with high credit-ratings (minimum A3/A-) assigned by international credit-rating agencies. The banks are reviewed on a regular basis and deposits may be transferred during the year to mitigate credit risk. On each reporting date, the Company considers the risk of expected credit loss on bank deposits, including the hypothetical impact arising from the probability of default, which is considered in conjunction with the expected loss caused by default by banks with similar credit-ratings and attributes. In line with previous periods, this assessment did not reveal a material impairment loss, and accordingly no provision for expected credit loss has been recognized.

Since March 2020, in order to mitigate the concentration of credit risks on bank deposits and to preserve capital, a portion of the bank deposits have been placed into primarily U.S. government bonds, treasury bills, corporate bonds, and commercial papers. The Company's investment policy, approved by the Board of Directors, only allows investment in marketable securities having investment grade credit-ratings, assigned by international credit-rating agencies. Accordingly, the risk from probability of default is low. The risk of expected credit loss over marketable securities has been considered, including the hypothetical impact arising from the probability of default, which is considered in conjunction with the expected loss caused by default from securities with similar credit-rating and attributes. This assessment did not reveal a material expected credit loss, and accordingly no provision for expected credit loss has been recognized.

For other financial assets, including deposits and receivables, the credit risk is considered low and no provision for expected credit loss has been recognized.

Liquidity Risk Management

Historically, the risk of insufficient funds has been addressed through proceeds from sale of the Company's securities in private and public offerings.

Liquidity risk is managed by maintaining adequate cash reserves and banking facilities, and by matching the maturity profiles of financial assets (including marketable securities), with cash-forecasts (including payment profiles on liabilities). The risk of shortage of funds is monitored, using a liquidity planning tool, to ensure sufficient funds available to settle liabilities as they fall due.

Besides marketable securities and deposits, the Company's financial assets are recoverable within twelve months after the reporting date. Marketable securities have a weighted average duration of 6.0 and 17.3 months, for current (i.e., those maturing within twelve months after the reporting date) and non-current positions, respectively. The entire portfolio of marketable securities (current and non-current) has a weighted average duration of 11.2 months.

Maturity analysis for financial liabilities recognized in the consolidated statements of financial position are specified below.

	< 1 year	1-5 years	>5 years	Total contractual cash-flows	Carrying amount
			(EUR'000)		
December 31, 2020					
Lease liabilities	6,974	38,321	68,516	113,811	91,975
Trade payables and accrued expenses	21,897	—	—	21,897	21,897
Total financial liabilities	**28,871**	**38,321**	**68,516**	**135,708**	**113,872**

	< 1 year	1-5 years	>5 years	Total contractual cash-flows	Carrying amount
			(EUR'000)		
December 31, 2019					
Lease liabilities	6,020	19,405	17,606	43,031	36,619
Trade payables and accrued expenses	27,765	—	—	27,765	27,765
Total financial liabilities	**33,785**	**19,405**	**17,606**	**70,796**	**64,384**

Note 21—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 the Company's operations. Related parties also include undertakings in which such individuals have a controlling or joint controlling interest. Additionally, all group enterprises and associates are considered related parties.

Neither the Company's related parties or major shareholders hold a controlling, joint controlling, or significant interest in the Group.

The Company has entered into employment agreements with and issued warrants to Key Management Personnel. In addition, the Company pays fees for board tenure and board committee tenure to the independent members of the Board of Directors. Please refer to Note 7.

Transactions between the parent company and group enterprises comprise management and license fees, research and development services, and clinical supplies. These transactions have been eliminated in the consolidated financial statements. Transactions and outstanding balances with the associate VISEN are disclosed in Note 13. In addition, the parent company Ascendis Pharma A/S is jointly taxed with its Danish subsidiaries, where the current Danish corporation tax is allocated between the jointly taxed Danish companies. For further details, please refer to Note 10.

Indemnification agreements have been entered with the board members and members of senior management.

Except for the information disclosed above, the Company has 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 22—Investments in Group Enterprises

Ascendis Pharma A/S's (parent company) investments in Group enterprises at December 31, 2020, comprise:

Subsidiaries	Domicile	Ownership
Ascendis Pharma GmbH	Germany	100%
Ascendis Pharma, Inc.	USA	100%
Ascendis Pharma Endocrinology, Inc.	USA	100%
Ascendis Pharma Ophthalmology Division A/S	Denmark	100%
Ascendis Pharma Endocrinology Division A/S	Denmark	100%
Ascendis Pharma Bone Diseases A/S	Denmark	100%
Ascendis Pharma Growth Disorders A/S	Denmark	100%
Ascendis Pharma Oncology Division A/S	Denmark	100%

Associate	Domicile	Ownership
VISEN Pharmaceuticals	Cayman Island	50%

Note 23—Ownership

The following investors, or groups of affiliated investors, are known by us to beneficially own more than 5% of the Company's outstanding ordinary shares at December 31, 2020:

- T. Rowe Price Associates, Inc., USA
- Entities affiliated with RA Capital Management, LLC, USA
- Entities affiliated with Artisan Partners Limited Partnership, USA
- Entities affiliated with FMR LLC, USA
- Baker Bros. Advisors LP, USA
- Entities affiliated with Wellington Management Group LLP, USA
- Entities affiliated with Janus Henderson Group plc, United Kingdom

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 24—Subsequent Events

On January 8, 2021, the Company entered into an equity investment of $12.5 million in its associate VISEN as part of VISEN's $150 million Series B financing. Following VISEN's Series B financing, the Company retains approximately 44% of VISEN's issued and outstanding shares. As a result, Ascendis expects to recognize a non-cash gain in the first quarter of 2021 of €42.3 million. The Series B financing does not change the Company's accounting treatment of VISEN.

No other events have occurred after the reporting date that would influence the evaluation of these consolidated financial statements.

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	3/9/2021	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).					
2.3	Description of Share Capital and American Depositary Shares.					X
4.1(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	
4.1(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	
4.2(a)#	Reference is made to Exhibit 1.1.					
4.2(b)#	Form of Warrant Certificate for Warrants issued prior to December 2015.	F-1	12/18/2014	10.4(b)	333-201050	
4.2(c)#	Form of Warrant Certificate for Warrants issued since December 2015.	20-F	3/22/2017	4.4(c)	001-36815	
4.3#	Form of Indemnification Agreement for board members and senior management.	F-1	1/16/2015	10.5	333-201050	
4.4(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	
4.4(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	
4.5	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	
4.6	Lease Agreement dated September 7, 2015 between Ascendis Pharma A/S and Dades AS.	F-3	2/2/2016	10.1	001-36815	
4.7†	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	
4.8†	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	
4.9*	Supply Agreement dated January 1, 2019, between Ascendis Pharma A/S and Vetter Pharma International GMBH.	20-F	4/3/2019	4.11	001-36815	
4.10*	Manufacturing and Supply Agreement dated October 28, 2018, between Ascendis Pharma A/S and Carbogen Amcis AG.	20-F	4/3/2019	4.12	001-36815	
4.11*	Commercial Supply Agreement dated January 9, 2019, between Ascendis Pharma A/S and Fujifilm Diosynth Biotechnologies UK Limited.	20-F	4/3/2019	4.13	001-36815	
4.12*	Exclusive Licence Agreement dated November 7, 2018, between Ascendis Pharma Growth Disorders A/S and VISEN Pharmaceuticals (CNP).	20-F	4/3/2019	4.15	001-36815	
4.13*	Exclusive Licence Agreement dated November 7, 2018, between Ascendis Pharma Bone Diseases A/S and VISEN Pharmaceuticals (hGH).	20-F	4/3/2019	4.16	001-36815	
4.14*	Exclusive Licence Agreement dated November 7, 2018, between Ascendis Pharma Endocrinology Division A/S and VISEN Pharmaceuticals (PTH).	20-F	4/3/2019	4.17	001-36815	
4.15*	Tech Transfer and Manufacturing Services Agreement dated December 12, 2019 between Ascendis Pharma A/S and Lonza Ltd.	20-F	4/2/2020	4.16	001-36815	
4.16*	Multi-Year Packaging Agreement dated December 1, 2019 between Ascendis Pharma A/S and Sharp Corporation.	20-F	4/2/2020	4.17	001-36815	
4.17*	Amended and Restated Shareholders Agreement dated January 8, 2021, by and among Ascendis Pharma A/S and the parties set forth therein.					X

4.18*	Amendment Letter to the Exclusive Licence Agreement dated January 4, 2021 between Ascendis Pharma Growth Disorders A/S and VISEN Pharmaceuticals (CNP)	X
4.19*	Amendment Letter to the Exclusive Licence Agreement dated January 4, 2021 between Ascendis Pharma Endocrinology Division A/S and VISEN Pharmaceuticals (hGH)	X
4.20*	Amendment Letter to the Exclusive Licence Agreement dated January 4, 2021 between Ascendis Pharma Bone Diseases 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.

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: March 10, 2021

By: /s/ Scott T. Smith
Scott T. Smith
Senior Vice President, Chief Financial Officer (Principal Financial Officer)

Date: March 10, 2021

Exhibit 2.3

DESCRIPTION OF SHARE CAPITAL

Set forth below is a summary of certain information concerning our share capital as well as a description of certain provisions of our articles of association, the registration rights agreement entered into in December 2015 to which we and certain holders of American Depositary Shares, also referred to as ADSs, are parties or the 2015 Registration Rights Agreement, and relevant provisions of the Danish Companies Act (in Danish: Selskabsloven). Because the following is only a summary, it does not contain all of the information that may be important to you. The summary includes certain references to and descriptions of material provisions of our articles of association, the 2015 Registration Rights Agreement and Danish law in effect as of the date of our Annual Report on Form 20-F. The summary below does not purport to be complete and is qualified in its entirety by reference to applicable Danish Law and our articles of association and the 2015 Registration Rights Agreement, copies of which are incorporated by reference into our Annual Report on Form 20-F. Further, please note that ADS holders are not treated as our shareholders and do not have rights as a shareholder. For more information regarding the rights of ADS holders, see the section of this exhibit titled "Description of American Depositary Shares".

General

Our company was incorporated on September 21, 2006 as a private limited liability company (in Danish: *Anpartsselskab, or ApS*) under Danish law and is registered with the Danish Business Authority (in Danish: *Erhvervsstyrelsen*) in Copenhagen, Denmark under registration number 29918791. On December 17, 2007, our company was converted into a public limited liability company (in Danish: Aktieselskab, or A/S). Our company's headquarters and registered office is Tuborg Boulevard 12, DK-2900 Hellerup, Denmark.

Authorizations to our board of directors

As of December 31, 2020, 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 4,140,846 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 28, 2024.
- Our board of directors is authorized to increase our share capital by up to 9,000,000 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 May 28, 2024.
- Our board of directors is authorized to issue 762,569 warrants and to increase our share capital by up to 762,569 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. This authorization is valid until May 28, 2025.
- 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 9,000,000 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 May 28, 2024.
- 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 77,153,801 shares consisting of 77,153,801 shares with a nominal value of DKK 1 each.

The ADSs are listed on The Nasdaq Global Select Market under the symbol “ASND.”

Our warrants

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. As of December 31, 2020, our board of directors is authorized to issue 762,569 warrants in the period ending May 28 2025. As of December 31, 2020, there were outstanding 6,402,622 warrants to subscribe for our ordinary shares and such warrants had a weighted average exercise price of €65.72.

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. 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. For the purpose of implementing the capital increases necessary in connection with the exercise of warrants, our board of directors has been authorized to increase our share capital by one or more issuances of shares with a total nominal value corresponding to the number of warrants issued upon cash payment of the exercise price without any pre-emptive subscription rights to existing shareholders.

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 403,467 outstanding warrants, granted in the period 2012 to 2014, 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 52,323 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 5,772,274 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.

Registration rights

Under the 2015 Registration Rights Agreement, we were required to timely register with the SEC 1.0 million ordinary shares underlying 1.0 million ADSs (the “Fidelity Shares”), purchased by Fidelity Securities Fund: Fidelity Series Small Cap Opportunities Fund—Healthcare Sub and Fidelity Stock Selector Small Cap Fund—Health Care Sub on December 14, 2015. In addition, the owners of the Fidelity Shares are entitled to registration of the Fidelity Shares on Form F-3. In accordance with our obligations under the 2015 Registration Rights Agreement, we filed a resale registration statement in February 2016 to register for resale the Fidelity Shares.

Unless our ordinary shares are listed on a national securities exchange or trading system and a market for our ordinary shares not held in the form of ADSs exists, any registrable securities sold pursuant to an exercise of the registration rights will be sold in the form of ADSs.

Expenses of registration

Under the 2015 Registration Rights Agreement, we agreed to pay certain registration expenses of the holders of the shares registered pursuant to the registration rights described above, excluding, among other things, the expenses of counsel for Fidelity Securities Fund: Fidelity Series Small Cap Opportunities Fund—Healthcare Sub and Fidelity Stock Selector Small Cap Fund—Health Care Sub.

Expiration of registration rights

Under the 2015 Registration Rights Agreement, the registration rights described above will expire upon the earlier of a change of control event, the disposition of the Fidelity Shares or when the Fidelity Shares can be sold under Rule 144 or Regulation S of the Securities Act during any three-month period.

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 when thresholds of 10%, 15%, 20%, 25%, 50%, 90% or 100%, or 1/3 or 2/3 are reached or no longer reached.

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 2019 for a term expiring at the annual general meeting to be held in 2021; and a second class of directors ("Class II") who were elected at the annual general meeting held in 2020 for a term expiring at the annual general meeting to be held in 2022. 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, 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 the section titled "*Item 10 E. Additional Information—Taxation*" in our Annual Report on Form 20-F 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 10%, 15%, 20%, 25%, 50%, 90% or 100%, or 1/3 or 2/3 are reached or 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 must include information on the date of acquisition or disposal of the shares, the number and, if applicable, the share class, the full name, address and civil registration (CPR) number of the shareholder or the name, central business register (CVR) number and registered office of the enterprise. If the shareholder has no civil registration (CPR) number or central business (CVR) number, such notice must be accompanied by other documentation securing unambiguous identification of the shareholder. The notice must also include information on the denomination or nominal value of the shares and the voting rights attaching to the shares.

Pursuant to section 58a, we are 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 who ultimately holds or controls, directly or indirectly, a sufficient part of the ownership interests or voting rights or exercises control by other means, except for owners of companies whose ownership interests are traded on a regulated market or a similar market which is subject to a duty of disclosure in accordance with EU law or similar international standards.

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, which will, in the case of the annual general meeting, include the annual report, 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 exhibit. 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, loss, 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 have been 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.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

Depositary

The depositary for the ADSs is The Bank of New York Mellon. The Bank of New York Mellon's depositary office and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

American Depositary Shares

The Bank of New York Mellon, as depositary, registers and delivers the 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.

You may hold ADSs either (1) directly (a) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (b) by having ADSs registered in your name in the Direct Registration System, or (2) indirectly by holding a security entitlement in ADSs through your broker or other financial institution. If you hold ADSs directly, you are a registered ADS holder, also referred to as an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

The Direct Registration System, or DRS, is a system administered by The Depository Trust Company, also referred to as DTC, pursuant to which the depositary may register the ownership of uncertificated ADSs, which ownership is confirmed by periodic statements sent by the depositary to the registered holders of uncertificated ADSs.

ADS holders are not treated as shareholders and do not have shareholder rights. Danish law governs shareholder rights. The depositary is the holder of the ordinary shares underlying the ADSs. As a holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary and you, as an ADS holder, and all other persons directly and indirectly holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. A copy of the deposit agreement is incorporated by reference as an exhibit to the company's Annual Report on form 20-F. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADS. For directions on how to obtain copies of those documents, see the section titled "*Item 19—Exhibits*" in our Annual Report on Form 20-F.

Dividends and Other Distributions

How will you receive dividends and other distributions on the ordinary shares?

The depositary has agreed to pay you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, after deducting its fees and expenses. As an ADS holder, you will receive these distributions in proportion to the number of ordinary shares your ADSs represent.

Cash. We do not expect to declare or pay any cash dividends or cash distributions on our ordinary shares for the foreseeable future. The depositary will convert any cash dividend or other cash distribution we pay on the ordinary shares or any net proceeds from the sale of any ordinary shares, rights, securities or other entitlements into U.S. dollars if it can do so on a reasonable basis and at the then prevailing market rate, and can transfer the U.S. dollars to the United States. If that is not possible and lawful or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest. Before making a distribution, any taxes or other governmental charges, together with fees and expenses of the depositary that must be paid, will be deducted. See the section titled "*Item 10 E. Additional Information—Taxation*" in our Annual Report on Form 20-F for a

summary of certain tax consequences in respect of dividends or distributions to holders of ADSs. It will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.

Ordinary Shares. The depositary may distribute additional ADSs representing any ordinary shares we distribute as a dividend or free distribution to the extent reasonably practicable and permissible under law. The depositary will only distribute whole ADSs. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new ordinary shares. The depositary may sell a portion of the distributed ordinary shares sufficient to pay its fees and expenses in connection with that distribution.

Elective Distributions in Cash or Shares. If we offer holders of our ordinary shares the option to receive dividends in either cash or shares, the depositary, after consultation with us, may make such elective distribution available to you as a holder of the ADSs. We must first instruct the depositary to make such elective distribution available to you. As a condition of making a distribution election available to ADS holders, the depositary may require satisfactory assurances from us that doing so would not require registration of any securities under the Securities Act. There can be no assurance that you will be given the opportunity to receive elective distributions on the same terms and conditions as the holders of ordinary shares, or at all.

Rights to Purchase Additional Ordinary Shares. If we offer holders of our securities any rights to subscribe for additional ordinary shares or any other rights, the depositary may make these rights available to ADS holders. If the depositary decides it is not legal and practical to make the rights available but that it is practical to sell the rights, the depositary will use reasonable efforts to sell the rights and distribute the proceeds in the same way as it does with cash distributions. The depositary will allow rights that are not distributed or sold to lapse. In that case, you will receive no value for them.

If the depositary makes rights available to you, it will exercise the rights and purchase the ordinary shares on your behalf and in accordance with your instructions. The depositary will then deposit the ordinary shares and deliver ADSs to you. It will only exercise rights if you pay it the exercise price and any other charges the rights require you to pay and comply with other applicable instructions.

U.S. securities laws may restrict transfers and cancellation of the ADSs representing ordinary shares purchased upon exercise of rights. For example, you may not be able to trade these ADSs freely in the United States. In this case, the depositary may deliver restricted depositary shares that have the same terms as the ADSs described in this section except for changes needed to put the necessary restrictions in place.

Other Distributions. The depositary will send to you anything else we distribute to holders of deposited securities by any means it determines is equitable and practicable. If it cannot make the distribution proportionally among the owners, the depositary may adopt another equitable and practical method. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property.

However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. In addition, the depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution.

Neither we nor the depositary are responsible for any failure to determine that it may be lawful or feasible to make a distribution available to any ADS holders. We have no obligation to register ADSs, ordinary shares, rights or other securities under the Securities Act. This means that you may not receive the distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposit ordinary shares or evidence of rights to receive ordinary shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or share transfer taxes or fees, and delivery of any required endorsements, certifications or other instruments of transfer required by the depositary, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs at the depositary's corporate trust office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or share transfer taxes or fees, the depositary will transfer and deliver the ordinary shares and any other deposited securities underlying the ADSs to you or a person designated by you at the office of the custodian or through a book-entry delivery. Alternatively, at your request, risk and expense, the depositary will transfer and deliver the deposited securities at its corporate trust office, if feasible.

How can ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADRs to the depositary for the purpose of exchanging your ADRs for uncertificated ADSs. The depositary will cancel the ADRs and will send you a statement confirming that you are the owner of uncertificated ADSs. Alternatively, upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to you an ADR evidencing those ADSs.

Voting Rights

How do you vote?

You may instruct the depositary to vote the number of whole deposited ordinary shares your ADSs represent. The depositary will notify you of shareholders' meetings or other solicitations of consents and arrange to deliver our voting materials to you if we ask it to. Those materials will describe the matters to be voted on and explain how you may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary.

The depositary will try, as far as practical, and subject to the laws of Denmark and our Articles of Association, to vote or to have its agents vote the ordinary shares or other deposited securities as instructed by ADS holders.

The depositary will only vote or attempt to vote as you instruct or as described above. If we ask the depositary to solicit the ADS holders' instructions to vote and an ADS holder fails to instruct the depositary as to the manner in which to vote by the specified date, such ADS holder will be deemed to have given a discretionary proxy to a person designated by us to vote the number of deposited securities represented by its ADSs, unless we notify the depositary that we do not wish to receive a discretionary proxy, there is substantial shareholder opposition to the particular question, or the particular question would have an adverse impact on our shareholders.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your ordinary shares. 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 provided that any such failure is in good faith. This means that you may not be able to exercise your right to vote and there may be nothing you can do if your ordinary shares are not voted as you requested.

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we will try to give the depositary notice of any such meeting and details concerning the matters to be voted upon sufficiently in advance of the meeting date.

Except as described above, you will not be able to exercise your right to vote unless you withdraw the ordinary shares. However, you may not know about the shareholder meeting far enough in advance to withdraw the ordinary shares.

Fees and Expenses

What fees and expenses will you be responsible for paying?

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 For: ADSs must pay:	• 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
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	• Any cash distribution to you
$0.05 (or less) per ADS	• Distribution of securities distributed to holders of deposited securities which are distributed by the depositary 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	• Depositary services
$0.05 (or less) per ADS per calendar year	• 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
Registration or transfer fees	• Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement)
Expenses of the depositary	• 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.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until such taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs registered in your name to reflect the sale and pay you any net proceeds, or send you any property, remaining after it has paid the taxes.

Reclassifications, Recapitalizations and Mergers

If we:	*Then:*
• Change the nominal or par value of our ordinary shares	The cash, ordinary shares or other securities received by the depositary will become deposited securities.
• Reclassify, split up or consolidate any of the deposited securities	Each ADS will automatically represent its equal share of the new deposited securities.
• Distribute securities on the ordinary shares that are not distributed to you	The depositary may also deliver new ADSs or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities. The depositary may also sell the new deposited securities and distribute the net proceeds if we are unable to assure the depositary that the distribution (a) does not require registration under the Securities Act or (b) is exempt from registration under the Securities Act.
• Recapitalize, reorganize, merge, liquidate, sell all or substantially all of our assets, or take any similar action	Any replacement securities received by the depositary shall be treated as newly deposited securities and either the existing ADSs or, if necessary, replacement ADSs distributed by the depositary will represent the replacement securities. The depositary may also sell the replacement securities and distribute the net proceeds if the replacement securities may not be lawfully distributed to all ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.

How may the deposit agreement be terminated?

The depositary will terminate the deposit agreement at our direction by mailing notice of termination to the ADS holders then outstanding at least 30 days prior to the date fixed in such notice for such termination. The depositary may also terminate the deposit agreement by mailing a notice of termination to us and the ADS holders if 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment.

After termination, the depositary and its agents will do the following under the deposit agreement but nothing else: collect distributions on the deposited securities, sell rights and other property, and deliver ordinary shares and other deposited securities upon cancellation of ADSs. Four months after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement for the pro rata benefit of the ADS holders that have not surrendered their ADSs. It will not invest the money and has no liability for interest. The depositary's only obligations will be to account for the money and other cash. After termination our only obligations under the deposit agreement will be to indemnify the depositary and to pay fees and expenses of the depositary that we agreed to pay and we will not have any obligations thereunder to current or former ADS holders.

Limitations on Obligations and Liability

Limits on our obligations and the obligations of the depositary; limits on liability to holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith;
- are not liable if either of us is prevented or delayed by law or circumstances beyond our control from performing our
- ligations under the deposit agreement;
- are not liable if either of us exercises, or fails to exercise, discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made
- available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- are not liable for any tax consequences to any holders of ADSs on account of their ownership of ADSs;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person; and
- may rely upon any documents we believe in good faith to be genuine and to have been signed or presented by the proper person.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances. Additionally, we, the depositary and each owner and holder, to the fullest extent permitted by applicable law, waive the right to a jury trial in an action against us or the depositary arising out of or relating to the deposit agreement.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of an ADS, make a distribution on an ADS, or permit withdrawal of ordinary shares, the depositary may require:

- payment of share transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any ordinary shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.
- The depositary may refuse to deliver ADSs or register transfers of ADSs generally when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Ordinary Shares Underlying Your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying ordinary shares at any time except:

- when temporary delays arise because: (1) the depositary has closed its transfer books or we have closed our transfer books; (2) the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting; or (3) we are paying a dividend on our ordinary shares;
- when you owe money to pay fees, taxes and similar charges; and
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

This right of withdrawal is not limited by any other provision of the deposit agreement.

Pre-release of ADSs

The deposit agreement permits the depositary to deliver ADSs before deposit of the underlying ordinary shares. This is called a pre-release of the ADSs. The depositary may also deliver ordinary shares upon cancellation of pre-released ADSs (even if the ADSs are canceled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying ordinary shares are delivered to the depositary.

The depositary may receive ADSs instead of ordinary shares to close out a pre-release. The depositary may pre-release ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made represents to the depositary in writing that it or its customer owns the ordinary shares or ADSs to be deposited; (2) the pre-release is fully collateralized with cash or other collateral that the depositary considers appropriate; and (3) the depositary must be able to close out the pre-release on not more than five business days' notice. In addition, the depositary will limit the number of ADSs that may be outstanding at any time as a result of prerelease to 30% of the number of deposited shares, although the depositary may disregard this limit from time to time if it determines it is appropriate to do so.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the DRS and Profile Modification System, or Profile, will apply to uncertificated ADSs upon acceptance thereof to DRS by DTC. DRS is the system administered by DTC under which the depositary may register the ownership of uncertificated ADSs and such ownership will be evidenced by periodic statements sent by the depositary to the registered holders of uncertificated ADSs. Profile is a required feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile System and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder Communications; Inspection of Register of Holders of ADSs; ADS Holder Information

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

[***] 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

AMENDED AND RESTATED SHAREHOLDERS AGREEMENT

THIS AMENDED AND RESTATED SHAREHOLDERS AGREEMENT (this "**Agreement**") is made and entered into as of January 8, 2021 by and among:

(1) VISEN Pharmaceuticals, a company established under the laws of Cayman Islands (the "**Company**");

(2) The Person(s) listed on Part I of Exhibit A hereto (each individually a "**Series A Investor**" and collectively, the "**Series A Investors**");

(3) The Person(s) listed on Part II of Exhibit A hereto (each individually a "**Series B Investor**" and collectively, the "**Series B Investors**"; the Series A Investors and the Series B Investors, collectively, the "**Investors**", and each individually, an "**Investor**");

(4) VISEN Pharmaceuticals HK Limited, a private company limited by shares and a wholly owned subsidiary of the Company established under the laws of Hong Kong (the "**HK Subsidiary**");

(5) VISEN Pharmaceuticals (Shanghai) Co., Ltd. (□□□□□□□□□□□□), a limited liability company and a wholly owned subsidiary of the HK Subsidiary incorporated under the laws of the People's Republic of China (excluding Hong Kong, Macao and Taiwan, the "**PRC**") (the "**WFOE**"); and

(6) VISEN Pharmaceuticals (BVI) Limited, a private company limited by shares and a wholly owned subsidiary of the Company established under the laws of the British Virgin Islands (the "**BVI Subsidiary**").

The Company, the HK Subsidiary, the WFOE and the BVI Subsidiary, together with all direct or indirect subsidiary of each (whether now in existence or formed in the future), 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, the HK Subsidiary, the WFOE and certain Investors are parties to that certain Shareholders Agreement dated as of November 7, 2018 (the "**Prior Agreement**").

B. The Company and the Series B Investors have entered into a 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 B preferred shares of the Company, par value US$0.0001 per share (the "**Series B Preferred Shares**") to the Series B Investors at the Closing.

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. The parties to the Prior Agreement now desire to amend and restate the Prior Agreement by entering into this Agreement.

E. 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 Preferred Shares representing no less than [***] percent ([***]%) of the Company's total issued and outstanding Ordinary Shares (calculated on a fully-diluted and as-converted basis) who is not a Competitor (as defined below) (each such holder of Preferred Shares, a "**Rights Holder**"):

(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;

(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 the holders of a majority of the issued and outstanding Series B Preferred Shares and Series A Preferred Shares (collectively, the "**Preferred Shares**"), voting together as a single class and on an as-converted basis (the "**Majority Preferred Shareholders**");

(iv) prior to thirty (30) days before the end of each fiscal year, an annual budget and business plan for the next fiscal year; and

(v) promptly upon the written request by any Rights Holder, such other information as such Rights Holder 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. Notwithstanding the foregoing, the Company or any of the Group Companies shall not be obligated pursuant to this Section 1.1(a)(v) to provide access to (x) any information that it reasonably and in good faith considers to be a trade secret and the disclosure of which

would adversely affect the interest of the Group Companies, (y) any confidential information unless covered by an enforceable confidentiality agreement, in form reasonably acceptable to the Company, or (z) any information the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel. The rights set forth above shall be collectively referred to as the "**Information Rights**".

All financial statements to be provided to any Rights Holder 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.

For the purpose of this Agreement, a "**Competitor**" means any Person that engages directly or indirectly in the Competing Business, and for the avoidance of doubt, a Competitor shall not include (x) Ascendis to the extent it complies with its relevant obligations under Section 9.6 of this Agreement; (y) any other Investor that is a Party to this Agreement as of the date hereof or any of its Affiliates (as defined below); and (z) any other institutional investment fund, private equity or venture capital fund, collective investment vehicle or similar investment organization that, together with its Affiliates, does not hold more than [***] percent ([***]%) of the outstanding equity securities (or other securities convertible into or exchangeable or exercisable for equity securities) in any Person (other than any Group Company) engaged in the Competing Business and is not an Affiliate of any Person (other than any Group Company) engaged in the Competing Business.

(b) Inspection Rights. The Company further covenants and agrees that, commencing on the date of this Agreement, each Rights Holder 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. Notwithstanding the foregoing, the Company or any of the Group Companies shall not be obligated pursuant to this Section 1.1(b) to provide access to (x) any information that it reasonably and in good faith considers to be a trade secret and the disclosure of which would adversely affect the interest of the Group Companies, (y) any confidential information unless covered by an enforceable confidentiality agreement, in form reasonably acceptable to the Company, or (z) any information the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

1.2 Board of Directors. The Second 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**", each director of the Board, a "**Director**" and collectively, the "**Directors**") shall consist of six (6) 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 two (2) Directors, who shall initially be Jan Moller Mikkelsen and Michael Wolff Jensen (each, an "**Ascendis Director**," and collectively, the "**Ascendis Directors**"), and the Ascendis Directors can only be removed by Ascendis; one of the Ascendis Directors shall serve as the chairman of the Board (the "**Chairman**"), and in the case of an equality of votes, the Chairman shall have a casting vote,

(b) Vivo Capital shall be entitled to appoint 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 Directors, the "**Series A Directors**") and shall be entitled to appoint one (1) such Director as a member to any committee of the Board, and the Vivo Capital Directors can only be removed by Vivo Capital,

(c) the person then serving as the Chief Executive Officer of the Company shall be appointed as a Director of the Company (the "**CEO Director**"), provided that if for any reason the CEO Director shall cease to serve as the Chief Executive Officer of the Company, the Majority Preferred Shareholders shall (i) remove the former Chief Executive Officer of the Company from the Board if such person has not resigned as a member of the Board; and (ii) elect such person's replacement as Chief Executive Officer of the Company as the new CEO Director, and

(d) so long as Sequoia continues to hold at least [***] Series B Preferred Shares (as adjusted for share dividends, subdivisions, consolidations, splits, combinations, recapitalizations or similar events), Sequoia shall be entitled to appoint one (1) Director, who shall initially be Yibo CAO (the "**Series B Director**", together with the Series A Directors, collectively, the "**Investor Directors**" and each an "**Investor Director**"), and the Series B Director can only be removed by Sequoia for so long as Sequoia is entitled to appoint the Series B Director.

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 at least two-thirds (2/3) of the Investor Directors including the Series B Director. If within two (2) hours from the time appointed for the meeting a quorum is not present, the meeting shall stand adjourned to the same time and place three (3) Business Days later or such other place as the Directors by unanimous consent may determine, and if at the adjourned meeting a quorum is not present within two (2) hours from the time appointed for the meeting and if a requisite quorum is not achieved based on the failure to attend such meeting by any Investor Director, then the quorum at such adjourned meeting shall be a majority of the Directors then in office, which for the avoidance of doubt may include the CEO Director. The Company shall reimburse the Directors for all reasonable out-of-pocket expenses incurred in connection with attending any meetings of the Board and any committee thereof. Notwithstanding the foregoing, if a majority of the Series A Directors or the Series B Director is not present at such adjourned meeting, no resolution may be adopted at such adjourned meeting with respect to the matters set forth in Section 7.22(A) or Section 7.2(B), as applicable, but the adoption of the resolution with respect to such matters shall be deferred to a second adjourned meeting, which shall be held at the same time and place two (2) Business Days later or such other place as the Directors by unanimous consent may determine, and if a majority of the Series A Directors or the Series B Director, as applicable, is still not present at such second adjourned meeting, the affirmative vote or written consent of a majority of the Series A Directors or the Series B Director, as applicable, for such matters shall no longer be required for the purpose of adopting the resolutions of the Board or any board of directors of any subsidiaries (if applicable) in connection with the matters set forth in Section 7.22(A) or Section 7.2(B), as applicable.

1.3 Observers.

(a) Vivo Capital shall be entitled to appoint one (1) observer (an "**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); provided, however, that the Observer shall agree to hold in confidence all information so provided; and provided further, that the Company reserves the right to withhold any information and to exclude the Observer from any meeting or portion thereof if access to such information or attendance at such meeting could adversely affect the attorney-client privilege between the Company and its counsel or result in disclosure of trade secrets or a conflict of interest, or if such Observer is a Competitor.

(b) Ascendis shall be entitled to appoint one (1) 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); provided, however, that the Observer shall agree to hold in confidence all information so provided; and provided further, that the Company reserves the right to withhold any information and to exclude the Observer from any meeting or portion thereof if access to such information or attendance at such meeting could adversely affect the attorney-client privilege between the Company and its counsel or result in disclosure of trade secrets or a conflict of interest, or if such Observer is a Competitor.

(c) So long as Sofinnova continues to hold at least [***] Preferred Shares (as adjusted for share dividends, subdivisions, consolidations, splits, combinations, recapitalizations or similar events), Sofinnova shall be entitled to appoint one (1) 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); provided, however, that the Observer shall agree to hold in confidence all information so provided; and provided further, that the Company reserves the right to withhold any information and to exclude the Observer from any meeting or portion thereof if access to such information or attendance at such meeting could adversely affect the attorney-client privilege between the Company and its counsel or result in disclosure of trade secrets or a conflict of interest, or if such Observer is a Competitor.

(d) So long as Sherpa continues to hold at least [***] Series B Preferred Shares (as adjusted for share dividends, subdivisions, consolidations, splits, combinations, recapitalizations or similar events), Sherpa shall be entitled to appoint one (1) 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); provided, however, that the Observer shall agree to hold in confidence all information so provided; and provided further, that the Company reserves the right to withhold any information and to exclude the Observer from any meeting or portion thereof if access to such information or attendance at such meeting could adversely affect the attorney-client privilege between the Company and its counsel or result in disclosure of trade secrets or a conflict of interest, or if such Observer is a Competitor.

1.4 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 to the extent practicable, as soon as possible after the Closing or the formation of such relevant Subsidiary, as applicable. In the event one or more Ascendis Directors is appointed to serve on the board of directors of the WFOE, one Ascendis Director shall serve as the chairman of the board of directors of the WFOE and have a casting vote in the case of an equality of votes to the extent permitted under the applicable laws.

1.5 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.

1.6 Termination. The provisions set forth under this Section 1 shall terminate upon the earliest to occur of (i) the consummation of the Qualified Initial Public Offering (as defined below), (ii) the consummation of an IPO (as defined below) in a Recognized Exchange (as defined below) duly approved by the Board where all Preferred Shares are converted into Ordinary Shares, or where such provisions are required to be terminated by applicable laws or stock exchange requirements; or (iii) the closing of a Deemed 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 Preferred Shares, (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 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 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 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 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 Registrable Securities 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 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 Deemed 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; or (iii) the third (3rd) anniversary of 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 (each, a "**Recognized 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**").

3. RIGHT OF PARTICIPATION.

3.1 General. Each holder of Preferred Shares, including each holder of 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**"). A Participation Rights Holder shall be entitled to apportion the Right of Participation hereby granted to it in such proportions as it deems appropriate, among (i) itself and (ii) its Affiliates; provided that each such Affiliate (x) is not a Competitor, and (y) agrees to enter into this Agreement.

3.2 Pro Rata Share. 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) held by all the Participation Rights Holders 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 Preferred Shares, Ordinary Shares, Non-voting Ordinary Shares or other voting shares of the Company and rights, options or warrants to purchase such Preferred Shares, Ordinary Shares, Non-voting Ordinary Shares and securities of any type whatsoever that are, or may become, convertible or exchangeable into such Preferred Shares, Ordinary Shares, Non-voting Ordinary Shares or other voting shares, provided, however, that the term "**New Securities**" shall not include the Exempted Securities (as defined in the Restated Articles).

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 immediately prior to the issuance of the New Securities giving rise to the Right of Participation.

(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 earliest to occur of (i) the consummation of the Qualified Initial Public Offering, (ii) the consummation of an IPO in a Recognized Exchange duly approved by the Board where all Preferred Shares are converted into Ordinary Shares, or where such provisions are required to be terminated by applicable laws or stock exchange requirements; or (iii) the closing of a Deemed Liquidation Event.

4. TRANSFER RESTRICTIONS.

4.1 Certain Definitions. For purposes of this Section 4, "**Ordinary Shares**" means (i) the Company's outstanding Ordinary Shares (other than those issued upon conversion of any Preferred Shares), (ii) the Company's outstanding Non-voting Ordinary Shares, and (iii) the Ordinary Shares and the Non-voting Ordinary Shares issuable upon exercise of outstanding options or warrants; "**Preferred Shareholder**" means the holder of Series A Preferred Shares and/or holder of Series B Preferred Shares of the Company; "**Ordinary Shareholder**" means a holder of any Ordinary Share of the Company; and "**Shareholder**" means a Preferred Shareholder or an Ordinary Shareholder.

4.2 Right of First Refusal. Subject to Section 4.4 and Section 4.5 of this Agreement, if any Ordinary Shareholder proposes to directly or indirectly (including through a holding entity, special purpose vehicle, or by any similar methods) sell, assign, pledge, hypothecate, transfer, exchange 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 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 Company and the Non-Selling Shareholders may exercise their right of first refusal with respect to the Offered Shares as follows:

(a) Option of the Company.

(i) The Company shall have a first option for a period of fifteen (15) Business Days from receipt of the Transfer Notice (the "**Company's 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 "**Company's Right of First Refusal**"). The Company may exercise the Company's Right of First Refusal and purchase all or any portion of the Offered Shares by notifying the Selling Shareholder in writing (the "**Company's First Refusal Notice**") before expiration of Company's First Refusal Period as to the number of shares that it wishes to purchase.

(ii) In the event that the Company has declined to exercise its rights to purchase all, or a portion of, the Offered Shares or fails to deliver the Company's First Refusal Notice within the Company's First Refusal Period, then the Selling Shareholder shall, within three (3) days after the expiration of the Company's First Refusal Period, give each Non-Selling Shareholders a "**Secondary Transfer Notice**" which shall identify the Offered Shares with respect to which the Company has declined to purchase or failed to exercise its right of first refusal (the "**Remaining Shares**").

(b) Option of the Preferred Shareholders.

(i) Each Non-Selling Shareholder shall have an option for a period of twenty (20) Business Days from receipt of the Secondary Transfer Notice (the "**Preferred Shareholders' First Refusal Period**") to elect to purchase the Remaining Shares at the same price and subject to the same terms and conditions as described in the Transfer Notice (the "**Preferred Shareholders' Right of First Refusal**"). Each Non-Selling Shareholder may exercise the Preferred Shareholders' Right of First Refusal and purchase all or any portion of the Remaining Shares by notifying the Selling Shareholder, the Company and each other Non-Selling Shareholder in writing (the "**Preferred Shareholders' First Refusal Notice**") before expiration of Preferred Shareholders' First Refusal Period as to the number of shares that it wishes to purchase. The Preferred Shareholders' First Refusal Notice shall set forth the number of Remaining 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 Remaining Shares available under Section 4.2(a)(i) within the Preferred Shareholders' First Refusal Period, then the Selling Shareholder shall promptly give written notice (the "**Preferred Shareholders' Overallotment Notice**") to each Non-Selling Shareholder that has elected to purchase all of its First Refusal Allotment of the Remaining Shares (each a "**Fully Participating Preferred Shareholder**"), which notice shall set forth the number of Remaining Shares not purchased by the other Non-Selling Shareholders

("**Preferred Shareholders' Overallotment Shares**"), and shall offer the Fully Participating Preferred Shareholders the right to acquire its First Refusal Allotment of the Preferred Shareholders' Overallotment Shares. Each Fully Participating Preferred Shareholder shall have five (5) Business Days after receipt of the Preferred Shareholders' Overallotment Notice (the "**Preferred Shareholders' Overallotment Period**") to deliver a written notice to the Selling Shareholder (the "**Participating Preferred Shareholders' Overallotment Notice**") of its election to purchase its First Refusal Allotment of the Preferred Shareholders' Overallotment Shares on the same terms and conditions as set forth in the Transfer Notice, which such Participating Preferred Shareholders' Overallotment Notice shall also indicate the maximum number of the Preferred Shareholders' Overallotment Shares that such Fully Participating Preferred Shareholder will purchase in the event that any other Fully Participating Preferred Shareholder elects not to purchase its First Refusal Allotment of the Preferred Shareholders' Overallotment Shares.

(c) First Refusal Allotment. Each Non-Selling Shareholder shall have the right to purchase that number of the Remaining Shares or 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 Remaining Shares or 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 Remaining Shares or Preferred Shareholders' Overallotment Shares, as applicable, unless it exercises its right of first refusal within the Preferred Shareholders First Refusal Period or the Preferred Shareholders' Overallotment Period, as applicable, to purchase up to all of its First Refusal Allotment of the Remaining Shares or Preferred Shareholders' Overallotment Shares, as applicable.

(d) Purchase Price and Payment. The purchase price for the Offered Shares to be purchased by the Company and/or 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 B Director and a majority 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) Business 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.

(e) Expiration Notice. Within five (5) days after the expiration of the 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 Company and/or the Non-Selling Shareholders exercising their rights of first refusal, or (ii) that the Company and/or 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 Preferred Shares described in Section 4.3 below.

(f) Rights of a Selling Shareholder. If the Company and/or 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 Company and/or such 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 the Company and/or 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 the Company and/or such Non-Selling Shareholder, and the Company shall update its register of members accordingly.

4.3 Preferred Shareholder's Co-Sale Right. In the event that the Company and the Non-Selling Shareholders have not exercised their right of first refusal with respect to 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 Non-Selling Shareholder who has 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 Non-Selling 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 Non-Selling 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 Non-Selling Shareholder. To the extent one or more of the Non-Selling Shareholder exercise such co-sale right 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 Non-Selling Shareholder shall be subject to the following terms and conditions:

(a) Co-Sale Pro Rata Portion. Each Non-Selling 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 Non-Selling 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 Non-Selling Shareholders who elect to exercise their co-sale rights (if any Non-Selling 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 Non-Selling 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 Non-Selling Shareholder elects to sell;

(ii) that number of Preferred Shares which is at such time convertible into the number of Ordinary Shares that such Non-Selling Shareholder elects to sell; provided in such case that, if the prospective purchaser objects to the delivery of Preferred Shares in lieu of Ordinary Shares, such Non-Selling Shareholder shall convert such 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 Preferred Shareholder. The share certificate or certificates that the participating Non-Selling 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 Non-Selling Shareholder that portion of the sale proceeds to which such Non-Selling 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 Non-Selling 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 Non-Selling Shareholder.

(d) Right to Transfer. To the extent the Non-Selling Shareholders do not elect to participate in the sale of the Offered Shares subject to the Transfer Notice, the Selling Shareholder may, not later than ninety (90) Business Days following delivery to the Company and each of the Non-Selling 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 Company and/or 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 Company and the Non-Selling 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 Company and the Non-Selling Shareholders and the co-sale right of the Non-Selling 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 Company and/or the 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 Controlled Affiliates, provided that the transferring 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 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) Until the Qualified Initial Public Offering, none of the Ordinary Shareholders shall, without the prior written approval of the Majority Preferred Shareholders, directly or indirectly Transfer through one or a series of transactions any Ordinary Shares held by it to any person.

(b) No Shareholder may directly or indirectly Transfer any Shares to any Competitor.

(c) 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 (as defined in Section 12.6 below) 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, AS AMENDED AND RESTATED FROM TIME TO TIME, 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 Termination. The provisions under this Section 4 shall terminate upon the earliest to occur of (i) the consummation of the Qualified Initial Public Offering, (ii) the consummation of an IPO in a Recognized Exchange duly approved by the Board where all Preferred Shares are converted into Ordinary Shares, or where such provisions are required to be terminated by applicable laws or stock exchange requirements; or (iii) the closing of a Deemed Liquidation Event.

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 Rights Holder, 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 Preferred Shares under Section 3 and each holder of Preferred Shares under Section 4 are fully assignable in connection with a transfer of shares of the Company by such holder of 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 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 the Company and the persons or entities holding (a) at least [***] percent ([***]%) of the Series A Preferred Shares then outstanding and (b) at least [***] percent ([***]%) of the Series B Preferred Shares then outstanding; 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 any holder of Preferred Shares hereunder in a manner disproportionate to any adverse effect such amendment or waiver would have on such other holder without the consent of such disproportionately affected holder, and (ii) any holder of Preferred Shares may waive any of its rights hereunder without obtaining the consent of any other holders of Preferred Shares or their assigns; provided, further, however, that (1) Sections 1.1(a), 1.2(a), 1.3(b), 1.4, 7.1(A)(m) and 9.6 of this Agreement and this proviso (1) shall not be amended or waived without the express written consent of Ascendis, (2) Sections 1.1(a), 1.2(b), 1.3(a), 7.1(A)(m) and 9.6 of this Agreement and this proviso (2) shall not be amended or waived without the express written consent of Vivo Capital, (3)

Sections 1.1(a), 1.2(d), 7.2(B) and 9.6 of this Agreement and this proviso (3) shall not be amended or waived without the express written consent of Sequoia, (4) Section 1.3(c) of this Agreement and this proviso (4) shall not be amended or waived without the express written consent of Sofinnova, and (5) Section 1.3(d) of this Agreement and this proviso (5) shall not be amended or waived without the express written consent of Sherpa. Any amendment or waiver effected in accordance with this Section 5.2 shall be binding upon each Party 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 Investor'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 and the rules of any stock exchange), 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 a Person, any other Person that, directly or indirectly, Controls, is Controlled by or is under common Control with such Person. In the case of an Investor other than Sequoia, the term "Affiliate" also includes (w) any direct or indirect shareholder of such Person, (x) any of such Person's general partners or limited partners, (y) the fund manager managing such Person (and general partners, limited partners and officers thereof) and other funds managed by such fund manager, (z) trusts Controlled by or for the benefit of any such Person referred to in (w), (x) or (y), and (z) any fund or holding company formed for investment purposes that is promoted, sponsored, managed, advised or serviced by Persons or any of their Affiliates. Notwithstanding the foregoing, the Parties acknowledge and agree that (A) the name "Sequoia" is commonly used to describe a variety of entities (collectively, the "**Sequoia Entities**") that are affiliated by ownership or operational relationship and engaged in a broad range of activities related to investing and securities trading and (B) notwithstanding any other provision of this Agreement to the contrary, this Agreement shall not be binding on, or restrict the activities of, any (1) Sequoia Entity outside of the Sequoia China Sector Group , (2) entity primarily engaged in investment and trading in the secondary securities market; (3) the ultimate beneficial owner of a Sequoia Entity (or its general partner or ultimate general partner) who is a natural Person, and such Person's relatives (including but

without limitation, such Person's spouse, parents, children, siblings, mother-in-law and father-in-law and brothers and sisters-in-law), (4) any officer, director or employee of a Sequoia Entity (or its general partner or ultimate general partner) and such Person's relatives, and (5) for the avoidance of doubt, any portfolio companies of any Sequoia Entity and portfolio companies of any affiliated investment fund or investment vehicle of any Sequoia Entity. For purposes of the foregoing, the "**Sequoia China Sector Group**" means all Sequoia Entities (whether currently existing or formed in the future) that are principally focused on companies located in, or with connections to, the People's Republic of China that are exclusively managed by Sequoia. 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 confidential information covered in Section 6.1 above 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 prior written consent of Ascendis, Vivo and Sequoia (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 and the rules and regulations of any stock exchange).

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.

(A) In addition to and subject to such other limitations as may be provided in the Restated Articles, so long as at least [***] Series A Preferred Shares (as adjusted for share dividends, subdivisions, consolidations, splits, combinations, recapitalizations or similar events) remain outstanding, 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, carry out any of the following actions except with the approval of holders of at least [***] percent ([***]%) of the Series A Preferred Shares then outstanding, via written consent or affirmative vote at a meeting, 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 in a manner that adversely affects the powers, preferences or rights of the Series A Preferred Shares;

(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, Non-voting 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 Deemed 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 Preferred Shares or pursuant to the ESOP Plan (as defined below) or other 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, Ordinary Shares, or issuance of any Ordinary Shares except for issuance under the ESOP Plan (as defined below) or conversion of Preferred 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 number of shares reserved under such plan);

(l) any increase or decrease in the authorized number of members of the board of directors of any Group Company, or change the manner in which the directors are appointed; and

(m) 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 sub-clauses (a) through (m) above requires a resolution of the shareholders, and if the shareholders vote in favor of such act but the approval of the holders of at least [***] percent ([***]%) of the Series A Preferred Shares then outstanding has not yet been obtained in accordance with this Section 7.1, the holders of Series A Preferred Shares that voted 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 favor of the resolution plus one (1).

(B) In addition to and subject to such other limitations as may be provided in the Restated Articles, so long as at least [***] Series B Preferred Shares (as adjusted for share dividends, subdivisions, consolidations, splits, combinations, recapitalizations or similar events) remain outstanding, 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, carry out any of the following actions except with the approval of holders of at least [***] percent ([***]%) of the Series B Preferred Shares then outstanding, via written consent or affirmative vote at a meeting, 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 in a manner that adversely affects the powers, preferences or rights of the Series B Preferred Shares;

(b) any amendment, modification or change of any rights, preferences, privileges or powers of, or any restrictions provided for the benefit of, the Series B Preferred Shares or any amendment, modification or change of any rights, powers or benefit attached to the Ordinary Shares, Non-voting 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 B Preferred Shares being prejudiced;

(c) liquidation, dissolution, winding up or reorganization of any Group Company, or any Deemed 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 Preferred Shares or pursuant to the ESOP Plan (as defined below) or other 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 B 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 B Preferred Shares, Ordinary Shares, or issuance of any Ordinary Shares except for issuance under the ESOP Plan (as defined below) or conversion of Preferred 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 number of shares reserved under such plan);

(l) any increase or decrease in the authorized number of members of the board of directors of any Group Company, or change the manner in which the directors are appointed; and

(m) 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 sub-clauses (a) through (m) above requires a resolution of the shareholders, and if the shareholders vote in favor of such act but the approval of the holders of at least [***] percent ([***]%) of the Series B Preferred Shares then outstanding has not yet been obtained in accordance with this Section 7.1, the holders of Series B Preferred Shares that voted 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 favor of the resolution plus one (1).

7.2 Approval by Board of Directors.

(A) In addition to such other limitations as may be provided in the Restated Articles and subject to Section 1.2 hereof, 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 approval of a majority of the Series A Directors, via written consent or affirmative vote at a meeting:

(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;

(j) enter into or be a party to any other transaction involving the payment, contribution or assignment by any Group Company or to any Group Company of assets greater than US$10,000,000, or any exclusive commercial relationship, in each case, other than in the ordinary course of business; or

(k) any agreement or commitment by any Group Company to do any of the foregoing.

(B) In addition to such other limitations as may be provided in the Restated Articles and subject to Section 1.2 hereof, 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 approval of the Series B Director, via written consent or affirmative vote at a meeting, for so long as Sequoia is entitled to appoint the Series B Director:

(a) make any loan or advance to 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) incur any aggregate indebtedness in excess of US$2,000,000 that is not already included in a Board-approved budget, other than trade credit incurred in the ordinary course of business;

(d) guarantee any indebtedness in excess of US$2,000,000 except for trade accounts of the Group Companies or any Subsidiary arising in the ordinary course of business;

(e) purchase or dispose of any business/assets of the Group Companies in excess of US$2,000,000 in aggregate, either in a single transaction or a series of related transactions, other than in the ordinary course of business;

(f) make equity investment in excess of US$5,000,000 in any subsidiary or other corporation, partnership, or other entity unless, immediately prior to the consummation of such equity investment, it is wholly owned by a Group Company;

(g) enter into or be a party to any other transaction involving the payment, contribution or assignment by any Group Company or to any Group Company of assets greater than US$10,000,000, or any exclusive commercial relationship, in each case, other than in the ordinary course of business; or

(h) agree or commit to do any of the foregoing.

7.3 Termination. The provisions set forth under this Section 7 shall terminate upon the earliest to occur of (i) the consummation of the Qualified Initial Public Offering, (ii) the consummation of an IPO in a Recognized Exchange duly approved by the Board where all Preferred Shares are converted into Ordinary Shares, or where such provisions are required to be terminated by applicable laws or stock exchange requirements; or (iii) the closing of a Deemed Liquidation Event.

8. DRAG ALONG.

8.1 In the event that (i) the holders of at least [***] ([***]) of the outstanding Preferred Shares (voting together as a single class and calculated 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 Deemed Liquidation Event, to a bona fide third party, or a group of bona fide related parties, whereby the gross proceeds derived from such transaction(s) shall be no less than US$[***] (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, Non-voting Ordinary Shares, Series A Preferred Shares and Series B 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 or the pro rata portion (calculated on an as-converted basis) 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 (i) 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, (ii) if applicable, such Remaining Shareholder is not required to make representations and warranties on any business and operational related matters, and (iii) such Remaining Shareholder is not required to agree (unless such Shareholder is a Company officer or employee) to any covenant not to compete or covenant not to solicit customers, employees or suppliers of any party to 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 or the pro rata portion (calculated on an as-converted basis) 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 this Agreement, none of the transfer restrictions set forth in this 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 U.S. Federal Income Tax. The Company is currently classified as a corporation (and not as a partnership) for U.S. federal income tax purposes and shall not take any action (including the making of any election) inconsistent with the Company's or any of its Subsidiaries' classification for U.S. federal income tax purposes as a corporation without the prior written consent of the Majority Preferred Shareholders.

9.4 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.

9.5 Additional 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, and shall use its best efforts to cause each Group Company to, comply in all material respects with all applicable Laws, rules, and regulations on a continuing basis. All material aspects of such formation, maintenance and compliance of each Group Company shall be subject to the review, approval and oversight by the Board.

9.6 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 less 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 (as defined in the Rights Agreements) 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 [***] percent ([***]%) or more 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 less than [***] percent ([***]%) immediately and in any event within [***] ([***]) months after the time when Ascendis comes to own directly or indirectly [***] percent ([***]%) or more of the issued share capital of such entity engaged in the Competing Business [***]. The provisions of this Section 9.6 shall terminate upon the earlier to occur of (i) the closing of a Deemed Liquidation Event; or (ii) the termination of each of the three Exclusive License Agreements, dated November 7, 2018, by and among the Company and each of 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 9.6 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. [***].

9.7 Management. Mr. Pony Lu and Dr. Dandan DONG have been nominated to serve as the Chief Executive Officer and Chief Business Officer of the Company, which nominations have been duly approved by the Board. The Company shall reasonably compensate for the services provided by Dr. Dandan DONG to the Group Companies.

9.8 ESOP. The Company shall cause each of the grantees under the employee equity incentive plan of the Company (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 pursuant to Section 4.2 above, in accordance with its pro rata ownership of the Company (on an as-converted basis), and if any Investor elects not 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 pursuant to Section 4.3 above. In addition, the Company shall ensure that each holder of the Non-voting 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 sixty (60) days of the 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 the Majority Preferred Shareholders or Ascendis, 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 Closing, each of the Group Companies shall (a) obtain in a timely manner and maintain all requisite Consents and Permits for conducting its principal business in compliance with all material aspects with applicable Laws, and (b) if so required by any applicable Laws, obtain additional Consents and Permits necessary for conducting its 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, including but not limited to completing the filing with human genetic resources authority of the PRC before transmission of or permitting any Person to transmit to Ascendis (or any Affiliate of Ascendis) any human genetic resources data derived from the phase III clinical trials of TransCon hGH conducted by the Group Companies in the Territory.

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 using such form that is satisfactory to the Majority Preferred Shareholders. The Group Companies shall cause each of their respective current and future employees and consultants to enter into a confidentiality, non-competition, non-solicitation and proprietary information and inventions assignment agreement using such form that is satisfactory to the Majority Preferred Shareholders.

9.12 Non-solicitation. The Group Companies shall not, and shall not permit any of its Subsidiaries or Affiliates or any of its or their respective directors, officers, managers, or employees to, directly or indirectly, solicit for employment or engagement, or employ or in any other way interfere with the employment relationship of any director, officer, senior member of management or any employee of: i) Ascendis or any of Ascendis' subsidiaries or Affiliates within the period that Ascendis or any of its Affiliates own, directly or indirectly, any of the shares of any Group Company and two years thereafter, except for any general solicitation that does not specifically target at the foregoing personnel, or ii) Sequoia or any of Sequoia's subsidiaries or Affiliates within the period that Sequoia or any of its Affiliates own, directly or indirectly, any of the shares of any Group Company and two years thereafter, except for any general solicitation that does not specifically target at the foregoing personnel.

9.13 Use of Name and Press. Without the written consent of any Investor, the Group Companies and any other Investors (excluding such Investor), shall not use the name or brand of such Investor or its Affiliate except to the extent such use is required pursuant to applicable laws or rules of stock exchange or is in the application materials for the IPO), claim itself as a partner of such Investor or its Affiliate, make any similar representations.

9.14 Compliance & Anti-Corruption. Upholding ethical standards, acting with integrity and in compliance with applicable laws and regulations, is essential to the Group Companies. Each of 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, directly or indirectly, to any third party, including any Non-U.S. Official (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) cease all of its or their respective activities, as well as remediate any actions taken by the Company, its Subsidiaries or Affiliates, or any of their respective directors, officers, managers, employees, contractors, representatives or agents 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. The Company hereby undertakes to adopt and implement anticorruption policy within ninety (90) days following the date hereof and export control policy within 360 days following the date hereof, in each case, mutually acceptable to the Company and Sequoia.

10. Termination and Consequences of Termination.

10.1 Termination. This Agreement (i) may be terminated at any time by written agreement among the holders of (a) at least [***] percent ([***]%) of the outstanding Series A Preferred Shares and (b) at least [***] percent ([***]%) of the outstanding Series B Preferred Shares; and (ii) shall be automatically terminated upon the dissolution of the Company

10.2 Effect of Termination. Upon the termination of this Agreement pursuant to Section 10.1 above, 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 that has incurred Losses (as defined below) as a result of such failure (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 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 as a result of a breach by a Breaching Party of any of its representations and warranties, covenants, undertakings, or other obligations under this Agreement.

(a) 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, CONSEQUENTIAL, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES OR LOST PROFITS. ABSENT ANY FRAUD, THE MAXIMUM INDEMNIFICATION LIABILITY OF ANY INVESTOR THAT IS A BREACHING PARTY UNDER THIS SECTION 11 SHALL BE LIMITED TO THE VALUE OF THE SHARES OF THE COMPANY HELD BY SUCH INVESTOR.

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 promptly at any time after the date hereof and before the expiration of the applicable statute of limitation, 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, unless disputed in good faith in writing, 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 Exclusive Remedy.

Except in the event of fraud and for equitable remedies, from and after the date hereof, the rights to indemnification under this Section 11 shall be the sole and exclusive monetary remedy of the Non-Breaching Parties with respect to any breach of this Agreement.

11.6 Director Indemnification.

To the fullest extent permitted by applicable Laws, as such may be amended from time to time, 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 to and activities on behalf of the Company.

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 that are not Competitors; 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; provided that this sentence shall terminate and be of no further force or effect pursuant to Section 4.8. For purposes of this Agreement, "**Person**" or "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, Series B Preferred Shares, Ordinary Shares or Non-voting Ordinary Shares of the Company, then, upon the occurrence of any subdivision, combination or share dividend of the Series A Preferred Shares, Series B Preferred Shares, Ordinary Shares or Non-voting 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, Series B Preferred Shares, Ordinary Shares or Non-voting 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 among 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. The complainant(s) and respondent(s) to such dispute shall each 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 agrees that it shall use its best effort to enhance and increase the value and principal business of the Group Companies. Further, to assist the Company to pursue a Qualified Initial Public Offering, each Shareholder agrees to cooperate with the Company proactively and in good faith, including answering requests within reasonable time.

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 Investor Directors. The Company, as a material part of the consideration for this Agreement, agrees that the Investors or the Investor 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 Investors' ability to pursue opportunities based on such Information or that would require the Investors, the Investor 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 B 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 B 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 a "Series B 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/ [***]
Name: [***]
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 Møller Mikkelsen
Name: Michael Wolff Jensen / Jan Møller Mikkelsen
Title: Chairman / CEO

ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S

By: /s/ Michael Wolff Jensen, /s/ Jan Møller Mikkelsen
Name: Michael Wolff Jensen / Jan Møller Mikkelsen
Title: Chairman / CEO

ASCENDIS PHARMA BONE DISEASES A/S

By: /s/ Michael Wolff Jensen, /s/ Jan Møller Mikkelsen
Name: Michael Wolff Jensen / Jan Møller Mikkelsen
Title: Chairman / CEO

ASCENDIS PHARMA GROWTH DISORDERS A/S

By: /s/ Michael Wolff Jensen, /s/ Jan Møller Mikkelsen
Name: Michael Wolff Jensen / Jan Møller Mikkelsen
Title: Chairman / CEO

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/ [***]
Name: [***]
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:

Sofinnova Venture Partners IX, L.P.
By: Sofinnova Management IX, L.L.C.
Its: General Partner

By: /s/ [***]
Name: [***]
Title: Managing Member

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:

SCC GROWTH VI HOLDCO F, LTD.

By: /s/ [***]
Name: [***]
Title: Authorized Signatory

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:

SHERPA HEALTHCARE FUND I, L.P.

By: /s/ [***]
Name: [***]
Title: Authorized Signatory

SHERPA HEALTHCARE CO-INVESTMENT FUND, L.P.

By: /s/ [***]
Name: [***]
Title: Authorized Signatory

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:

WORLDWIDE HEALTHCARE TRUST PLC
By: OrbiMed Capital LLC, solely in its capacity as Portfolio Manager

By: /s/ [***]
Name: [***]
Title: Authorized Signatory

ORBIMED GENESIS MASTER FUND, L.P.

By: OrbiMed Genesis GP LLC,
its General Partner

By: OrbiMed Advisors LLC,
its Managing Member

By: /s/ [***]
Name: [***]
Title: Authorized Signatory

ORBIMED NEW HORIZONS MASTER FUND, L.P.
By: OrbiMed New Horizons GP LLC, its General Partner
By: OrbiMed Advisors LLC, its Managing Member

By: /s/ [***]
Name: [***]
Title: Authorized Signatory

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:

CORMORANT GLOBAL HEALTHCARE MASTER FUND, LP

By: Cormorant Global Healthcare GP, LLC

By: /s/ [***]
Name: [***]
Title: Managing Member

CORMORANT PRIVATE HEALTHCARE FUND III, LP

By: Cormorant Private Healthcare GP, LLC

By: /s/ [***]
Name: [***]
Title: Managing Member

CRMA SPV, L.P.

By: Cormorant Asset Management, LP

By: /s/ [***]
Name: [***]
Title: Attorney-in-fact

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:

HBM HEALTHCARE INVESTMENTS (CAYMAN) LTD.

By: /s/ [***]
Name: [***]
Title: Managing 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:

LOGOS OPPORTUNITIES FUND II, L.P.
By: Logos Opportunities GP, LLC
Its General Partner

By: /s/ [***]
Name: [***]
Title: Managing Member

Address: 1 Letterman Drive
Building D, Suite D3-700
San Francisco, CA 94129

By: /s/ [***]
Name: [***]
Title: Managing Partner

Address: 1 Letterman Drive
Building D, Suite D3-700
San Francisco, CA 94129

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:

COSMIC CLOVER LIMITED

By: /s/ [***]
Name: [***]
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:

CRF INVESTMENT HOLDINGS COMPANY LIMITED

By: /s/ [***]
Name: [***]
Title: Director

EXHIBIT A

PARTIES

Part I Series A Investors

Name of Series A 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 IX, L.P. ("**Sofinnova**")	[***]
Total	[***]

Part II Series B Investors

Name of Series B Investors	Number of Series B Preferred Shares
SCC Growth VI Holdco F, Ltd. ("**Sequoia**")	[***]
Sherpa Healthcare Fund I, L.P. (together with Sherpa Healthcare Co-Investment Fund, L.P., collectively, "**Sherpa**")	[***]
Sherpa Healthcare Co-Investment Fund, L.P.	[***]
Worldwide Healthcare Trust PLC (together with OrbiMed Genesis Master Fund, L.P., OrbiMed New Horizons Master Fund, L.P., collectively, "**OrbiMed**")	[***]
OrbiMed Genesis Master Fund, L.P.	[***]
OrbiMed New Horizons Master Fund, L.P.	[***]
Cormorant Private Healthcare Fund III, LP (together with Cormorant Global Healthcare Master Fund, LP, CRMA SPV, L.P., collectively, "**Cormorant**")	[***]
Cormorant Global Healthcare Master Fund, LP	[***]
CRMA SPV, L.P.	[***]
HBM Healthcare Investments (Cayman) Ltd. ("**HBM**")	[***]
Logos Opportunities Fund II, L.P. ("**Logos**")	[***]
Cosmic Clover Limited ("**Pivotal**")	[***]
CRF Investment Holdings Company Limited ("**China Reform Overseas**")	[***]
Vivo Capital	[***]
Ascendis Pharma Endocrinology Division A/S	[***]
Ascendis Pharma Bone Diseases A/S	[***]
Ascendis Pharma Growth Disorders A/S	[***]
Sofinnova	[***]
TOTAL	[***]

EXHIBIT A

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: Room 2501 1788 Square No 1788 West Nanjing Road, Shanghai P.R.China
Attention: [***]
E-mail address: [***]

With a copy to:

Vivo Capital

Address: 505 Hamilton Avenue, Suite 207, Palo Alto, CA 94301
Tel: (650) 688-0818
Attention: [***]
E-mail address: [***]

and

Ascendis

Address: Tuborg Boulevard 12
2900 Hellerup
Denmark
Tel: +45 70 22 22 44
Attention: [***]
E-mail address: [***]

If to the Investors:

If to Ascendis

Tuborg Boulevard 12
2900 Hellerup
Denmark
Attention: [***]
E-mail address: [***]

If to Vivo Capital

505 Hamilton Avenue, Suite 207, Palo Alto, CA 94301
Tel: (650) 688-0818
Attention: [***]
E-mail address: [***]

EXHIBIT A

If to Sofinnova

3000 Sand Hill Road, Bldg. 4, Suite 250
Menlo Park, CA 94025
Attention: [***]
E-mail address: [***]

If to Sequoia

Address: Maples Corporate Services Limited PO Box 309 Ugland House Grand
Cayman, KY1-1104, Cayman Islands
c/o Suite 3613, Two Pacific Place, 88 Queensway, Hong Kong
Tel: (852) 2501 8989
Attention: [***]
E-mail address: [***]

If to Sherpa

Address: Huibin Plaza, No.8 East Beichen Road, Room-A901, Chaoyang District, Beijing,
China
Attention: [***]
E-mail address: [***]

If to OrbiMed

Address: 601 Lexington Avenue, 54th Floor, New York, NY 10022
Tel: (212) 739-6400
Attention: General Counsel
E-mail address: [***]

If to Cormorant

Address: 200 Clarendon Street 52nd Floor
Boston, MA 02116
Tel: 857 702 0386
Fax: 617 507 5905
Attention: [***]
E-mail address: [***]

If to HBM

Address: Governors Square, Suite #4-212-2
23 Lime Tree Bay Avenue
PO Box 30852
Grand Cayman, KY1-1204, Cayman Islands
Tel: ++1.345.946.8002
Attention: [***]
E-mail address: [***]

EXHIBIT A

If to Logos

Address: Logos Capital
1 Letterman Dr., Ste D3-700
San Francisco, CA 94129
Attention: [***]
E-mail address: [***]

If to Pivotal

Address: c/o 23/F Nan Fung Tower, 88 Connaught Road C, Central, Hong Kong
Tel: +852 3108 3633
Fax: +852 3162 5688
Attention: [***]

If to China Reform Overseas

Address: Suite 4704, Central Plaza, 18 Harbour Road, Wanchai, Hong Kong
Attention: [***]
E-mail address: [***]

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 January 8, 2021, 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.

[_____]

SIGNED, SEALED and DELIVERED

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.

VISEN Pharmaceuticals
P.O. Box 472
2nd Floor, Harbour Place
103 South Church Street
George Town, Grand Cayman KY1-1106
Cayman Islands

Attention: [***]

4 January, 2021

Amendment to the Exclusive Licence Agreement between Ascendis Pharma Growth Disorders A/S and Visen Pharmaceuticals dated 7 November 2018 (the "Agreement")

Dear Sirs or Madams

Further to the Parties' recent discussions regarding the Agreement, and in consideration of the Series B financing and the promises and mutual covenants set forth in this letter (including the appendix to this letter), we now wish to amend the Agreement as set out in the appendix to this letter.

These amendments shall take effect on and from the closing of the Series B financing. For the avoidance of doubt, all capitalised terms shall have the meaning given to them in the Agreement unless separately defined in this letter.

We confirm that all other terms and conditions of the Agreement remain unchanged and continue in full force and effect.

Please confirm your acceptance to these terms by countersigning this letter and the enclosed copy of this letter and returning the copy to us at [***] marked for the attention of [***], as soon as possible and, in any event, by 4 January 2021.

Yours faithfully

/s/ Jan Møller Mikkelsen
Jan Møller Mikkelsen, CEO

/s/ Michael Wolff Jensen
Michael Wolff Jensen, Chairman of the board of directors

for and on behalf of **Ascendis Pharma Growth Disorders A/S**

Accepted and agreed:

/s/ [***]

[***], Director 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.

Appendix : Amendments

1. A new definition of Ascendis Alliance Manager shall be inserted and read as follows:

   "Ascendis Alliance Manager" means an FTE individual designated by Ascendis to ensure communication and alignment between Ascendis and Licensee regarding activities carried out by either Party under this Agreement. The annual FTE rate of such Ascendis Alliance Manager shall be EUR [***]."

2. A new definition of Commercialisation Plan shall be inserted and read as follows:

   ""Commercialisation Plan" has the meaning ascribed to it in Clause 4.8."

3. A new definition of Good Pharmacovigilance Practice shall be inserted and read as follows:

   ""*Good Pharmacovigilance Practice" means the applicable principles and guidelines for good pharmacovigilance 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 European Medicines Agency's GVP modules I to XVI."*

4. A new definition of Technology Transfer Plan shall be inserted and read as follows:

   ""*Technology Transfer Plan" means: the plan mutually agreed and signed by the Parties for the transfer of Ascendis Technical Information from Ascendis to Licensee to the extent necessary to permit Licensee to Manufacture Licensed Products within the Territory. Such Technology Transfer Plan shall include (without limitation): (i) [***]."* All reasonable costs in accordance with the budget set forth in the technology Transfer Plan shall be covered by Licensee (including [***], all as agreed by Licensee in the Technology Transfer Plan).

5. Clause 4.3 of the Agreement shall be deleted and replaced with the following:

   "*The Licensee shall be solely responsible for any clinical trial activities carried out as part of its development and commercialisation activities in the Territory. For such clinical trials, Licensee shall coordinate with Ascendis so that clinical endpoints, inclusion and exclusion criteria for the clinical trial are aligned with clinical trials conducted by Ascendis outside the Territory in similar indications, unless specific deviations are requested by the Regular Authority in the Territory, in which case the Parties shall in good faith discuss to propose an acceptable endpoint, inclusion or exclusion criteria with the Regulatory Authorities. However, if clinical trials are performed in the Territory in respect of the Licensed Product as part of a single global study to support Regulatory Approval in at least [***] in respect of the Licensed Product ("Multi-territory Study/ies"), then the performance of such Multi-territory Studies in the Territory shall be subject to the Parties' mutual agreement and the Parties' agreement in advance, in writing, as to their respective obligations in respect of any such Multi-territory Study, including (without limitation) the Parties' respective responsibilities for: [***]. If the Parties are unable to agree such matters in advance, the Licensee shall not participate in such Multi-territory Study."*

[***] 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.

6. Clause 4.4 of the Agreement shall be amended to read as follows:

"The Licensee shall use Diligent Efforts to develop and commercialise Licensed Product in the Field in the Territory. The Licensee shall ensure that such development and commercialisation of the Licensed Product are consistent with the Research and Technical Development Plan and Commercialisation Plan."

7. Clause 4.5 of the Agreement shall be amended to read as follows:

"Each Party shall conduct all development of Licensed Product in compliance with Applicable Laws, which shall include Good Laboratory Practice, Good Clinical Practice, Good Pharmacovigilance 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."

8. A new Clause 4.7 shall be inserted into the Agreement and read as follows:

"*4.7 Joint Commercialisation Committee.*

(A) Formation of the JCC. At least [***] prior to the first commercial sale of the Licensed Product in the Field in the Territory, the Parties will form a Joint Commercialisation Committee comprised of [***] (the "JCC").

(B) One representative of the Licensee at the JCC will be selected to act as the chairperson of the JCC. The JCC will meet at least [***] ([***]) times per year and such meetings may be conducted by videoconference, teleconference or in person, as agreed by the Parties. The JCC 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 JCC 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 JCC members, any needed changes discussed and final minutes agreed to and provided to each Party within [***] after each meeting unless otherwise agreed. A reasonable number of additional representatives of a Party may attend meetings of the JCC in a non-voting capacity. Each Party is responsible for its personnel and travel costs and expenses associated with attending meetings.

(C) JCC functions and powers. The responsibilities of the JCC will be as follows:

(1) encouraging and facilitating communication between the Parties with respect to the commercialisation of Licensed Product(s)) in the Field in the Territory;

(2) [***] the first Commercialisation Plan pursuant to Clause 4.8;

(3) [***] the Commercialisation Plan [***] and [***];

(4) exchanging information on the progress of the commercialisation of the Licensed Product in the Field in the Territory; and

(5) carrying out the other duties and responsibilities described for it in this Agreement.

(D) JCC Decision Making. All decisions of the JCC will be made by unanimous vote, with each of Ascendis and Licensee having one vote and the decisions will be recorded in the JCC minutes. If after reasonable discussion and consideration of each of the Parties' views on a particular matter before the JCC, the JCC is unable to reach a decision by unanimous vote on that matter, the following shall apply:

(a) the disputed matter shall be [***];

(b) irrespective of above Clause 4.7 (D) (a), [***]. The JCC shall not have any authority other than that expressly set forth above and, specifically, shall have no authority: [***]

(E) Duration of the JCC. The JCC shall continue in full force and effect unless and until this Agreement expires or is terminated in accordance with Clause 18."

9. A new Clause 4.8 shall be inserted into the Agreement and read as follows:

"*4.8 Promptly following the establishment of the JCC, Licensee shall present to the JCC a plan setting out the commercial strategy for the commercialisation of the Licensed Products in the Field in the Territory including (without limitation) relating to branding, promotional materials, positioning in the market and medical affairs activities (including detailing), which with respect to content may not be inconsistent with the commercial strategy for the commercialisation of the Licensed Products in the Field outside the Territory) (the "Commercialisation Plan"). Such plan shall be [***] the JCC [***] thereafter no later than [***] and the JCC [***]."*

10. A new Clause 4.9 shall be inserted into the Agreement and read as follows:

"Promotional materials:

(A) Promotional materials including pre-marketing medical information material for the Licensed Products for use in the Territory shall be developed by the Licensee, comply with Applicable Laws and Regulatory Approvals (including approved label of the Licensed Product), and be scientifically accurate and consistent with data generated for the Licensed Product inside and outside the Territory. Copies of such materials shall be archived by the Parties to the extent required by Applicable Laws

(B) *The Licensee shall submit English translations of samples of all such promotional materials to Ascendis, in advance of being used, for Ascendis' review and comment. Ascendis shall provide any comment to Licensee in writing within [***] of receipt of such samples and Licensee shall consider such comments in good faith and incorporate such comments.*

(C) *The Licensee shall incorporate comments provided by Ascendis pursuant to above subsection 4.9 (B) to the extent they correct any scientific inaccuracy and / or correct any statements that are in contrast to any accurate statement regarding the Licensed Product used outside the Territory..*"

11. Clause 5.2(B) of the Agreement shall be amended to read as follows:

"*conduct all relevant packaging and distribution in accordance with Applicable Laws, which shall include Good Manufacturing Practice and Good Distribution Practice, in each case, to the extent applicable. In addition, Ascendis shall provide Licensee with written instructions in advance as to the best practice for handling and storing the Licensed Product and Licensee shall follow such instructions.*"

12. A new Clause 5.3 shall be inserted into the Agreement and read as follows:

"5.3 ***Technology Transfer***

5.3(A) If Licensee wishes to Manufacture Licensed Product in the Territory (including the TransCon [***], TransCon [***] or any other component which is proprietary to Ascendis or its CMO's and necessary for the manufacture of the Licensed Product, but excluding the TransCon [***]) by itself or (subject to prior approval in writing by Ascendis, not to be unreasonably withheld, delayed or conditioned) via its subcontractors, it shall notify Ascendis of the same in writing, and the Parties shall cooperate in good faith to agree on a Technology Transfer Plan to implement the transfer of such Ascendis Technical Information (after relevant approval from affected CMO's) to the extent necessary to permit Licensee to Manufacture the Licensed Products in the Territory. The Licensee shall be responsible for the following:

(a) the Manufacture of the Licensed Products by Licensee shall comply with standards required by the FDA and the European Medicines Agency, any International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidance, and Good Manufacturing Practice; and audited by Ascendis; and

(b) the Manufacturing process used following any technology transfer pursuant to this Clause 5.3 shall be, unless otherwise agreed to by Ascendis, identical or comparable (or modified solely to the extent necessary to meet local regulatory requirements) to the Manufacturing process used outside the Territory immediately prior to such technology transfer; and

(c) the Licensed Product manufactured by Licensee following a technology transfer shall be comparable to Licensed Product manufactured by Ascendis as determined in accordance with relevant guidelines issued by FDA and EMA. Licensee shall document in writing such comparability to Ascendis prior to any clinical or commercial use of Licensed Product by Licensee.

Licensee acknowledges and agrees that any such technology transfer may be subject to the consent of Ascendis' contract manufacturer(s) and any conditions and/or fees imposed by such contract manufacturer(s) in respect of the same. Ascendis shall seek the consent of such contract manufacturer(s) acting in good faith, provided that if such consent is not obtained, no transfer shall occur in respect of the activities performed by such contract manufacturer(s).

Promptly following the Parties agreeing to the content of the Technology Transfer Plan, the Parties shall perform the transfer from Ascendis or its contract manufacturer to Licensee (or its subcontractor if approved in writing by Ascendis) of the Ascendis Technical Information necessary to permit Licensee to Manufacture the Licensed Products in the Territory, in accordance with the relevant Technology Transfer Plan. Each Party shall use reasonable efforts to complete the tasks assigned to such Party under the Technology Transfer Plan in a timely manner and in accordance with the Technology Transfer Plan. Each Party shall designate qualified personnel having the necessary skill, expertise, and experience to facilitate such technology transfer and who shall be responsible for coordinating the technology transfer activities under the Technology Transfer Plan. Each Party shall cooperate with the other Party in such other Party's conduct of technology transfer activities under the Technology Transfer Plan. For the avoidance of doubt, such technology transfer shall not result in any change in the ownership or Control of any of the Ascendis Patents, Ascendis Technical Information, Ascendis Platform Technology, Ascendis Program IP or Joint Program IP, and all Technical Information so transferred to the Licensee for the Manufacture of Licensed Products constitutes Ascendis' Confidential Information. As between the Parties, Licensee shall be solely responsibility for obtaining and maintaining and shall own all Regulatory Approvals for its (or its subcontractor's) manufacture of Licensed Product from Regulatory Authorities in each of the jurisdictions in the Territory in the Field, and associated costs.

5.3(C) Licensee shall pay Ascendis' FTE Costs and travel costs incurred in the performance of the Technology Transfer Plan and all costs of any materials transferred to Licensee, in each case in accordance with the Technology Transfer Plan, subject to receipt of an invoice from Ascendis for such amounts. Licensee shall further pay any reasonable contract manufacturer's fees in connection with such technology transfer that Licensee agreed to pay as part of the Technology Transfer Plan. All other costs and expenses incurred by either Party in connection with the performance of the Technology Transfer Plan shall be borne by the incurring Party.

5.3(D) If, at any time after such technology transfer, the Manufacture of the Licensed Product by Licensee (or its subcontractors) fails to comply with Applicable Laws or the requirements set out in Clause 5.3(A)(a) – (c), then the Parties shall promptly confer and discuss an appropriate plan to remedy such failure for the future Manufacture of Licensed Product by Licensee (or its subcontractors)."

[***] 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.

13. Clause 6.4 shall be amended to read as follows:

"6.4 The Licensee undertakes to comply, and to procure that its Sub-Licensees and contractors comply, with all requirements of Regulatory Authorities, Applicable Laws, which shall include Good Laboratory Practice, Good Manufacturing Practice, Good Distribution Practice and Good Pharmacovigilance Practice, in each case to the extent applicable."

14. Clause 6.5 shall be amended to read as follows:

"Ascendis shall provide assistance and information as reasonably requested by the Licensee in support of such regulatory activities, [***]. In addition to [***], Licensee shall bear the cost for any additional services conducted by the Ascendis Alliance Manager for the Licensee that is not already reimbursed by Licensee otherwise (e.g., reimbursed as part of the research, development or regulatory assistance), [***], provided that the Parties shall mutually agree upon the scope and time to be spent on such additional services prior to the Ascendis Alliance Manager conducting any such services."

15. Clause 8 shall be amended to read as follows:

"Each Party will maintain complete and accurate books, records and accounts in connection with its performance of this Agreement (including, without limitation, those used for the determination of any payment obligations under this Agreement). Such 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 retain such books, records and accounts for an additional [***] ([***]) years if reasonably available and required by the applicable tax authority. During the term of the Agreement and for a period of [***] thereafter, each Party, its Affiliates and/or their nominee may review and inspect such books, records, and accounts for the sole purpose of determining such other Party's compliance with this Agreement (including, without limitation, compliance with Clauses 4, 5, 6, 7, 9 and 10). Such review and inspection shall not take place more than [***] and shall be subject to the inspecting Party giving the other Party reasonable advance notice of such review and inspection and such review and inspection shall take place during normal business hours at a mutually agreed upon time (such agreement not to be unreasonably withheld, delayed or conditioned). The inspecting Party shall bear its own expenses, and the other Party shall reasonably cooperate with the inspecting Party, its Affiliates and/or nominee, in connection with any inspection. To the extent that any significant deficiencies are identified as the result of such inspection, the inspected Party shall take all reasonable corrective measures to remedy any such significant deficiencies. For clarity, any review or inspection pursuant to this Clause 8 shall be subject to the terms of Clause 10 and this Clause 8 shall survive the termination or expiry of this Agreement for [***]."

[***] 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.

16. A new Clause 9.3 shall be inserted into the Agreement and read as follows:

"9.3 Each Party shall perform all pharmacovigilance in respect of the Licensed Product in compliance with Applicable Laws, which shall include Good Pharmacovigilance Practice to the extent applicable. As soon as practicable after the date of this letter, the Parties shall negotiate in good faith and enter into a pharmacovigilance agreement governing the pharmacovigilance activities of the Parties with respect to the Licensed Product."

17. This letter, once executed by both Parties, shall be deemed incorporated into the Agreement and all terms and conditions of the Agreement (including without limitation Clauses 1, 15, 18 (where Clauses 4.9 (A) and (C), 5.3(D), 6.4 and Clause 8 shall be added to the list of material obligations under Clause 18.2(b)), 19, 20 and 21), unless expressly modified in this letter, shall apply.

[***] 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.

VISEN Pharmaceuticals
P.O. Box 472
2nd Floor, Harbour Place
103 South Church Street
George Town, Grand Cayman KY1-1106
Cayman Islands

4 January, 2021

Attention: [***]

Amendment to the Exclusive Licence Agreement between Ascendis Pharma Endocrinology Division A/S and Visen Pharmaceuticals dated 7 November 2018 (the "Agreement")

Dear Sirs or Madams

Further to the Parties' recent discussions regarding the Agreement, and in consideration of the Series B financing and the promises and mutual covenants set forth in this letter (including the appendix to this letter), we now wish to amend the Agreement as set out in the appendix to this letter.

These amendments shall take effect on and from the closing of the Series B financing. For the avoidance of doubt, all capitalised terms shall have the meaning given to them in the Agreement unless separately defined in this letter.

We confirm that all other terms and conditions of the Agreement remain unchanged and continue in full force and effect.

Please confirm your acceptance to these terms by countersigning this letter and the enclosed copy of this letter and returning the copy to us at [***] marked for the attention of [***], as soon as possible and, in any event, by 4 January 2021.

Yours faithfully

/s/ Jan Møller Mikkelsen
Jan Møller Mikkelsen, CEO

/s/ Michael Wolff Jensen
Michael Wolff Jensen, Chairman of the board of directors

for and on behalf of **Ascendis Pharma Endocrinology Division A/S**

Accepted and agreed:

/s/ [***]

[***], Director 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.

Appendix : Amendments

1. A new definition of Ascendis Alliance Manager shall be inserted and read as follows:

   "Ascendis Alliance Manager" means an FTE individual designated by Ascendis to ensure communication and alignment between Ascendis and Licensee regarding activities carried out by either Party under this Agreement. The annual FTE rate of such Ascendis Alliance Manager shall be EUR [***]."

2. A new definition of Commercialisation Plan shall be inserted and read as follows:

   ""Commercialisation Plan" has the meaning ascribed to it in Clause 4.8."

3. A new definition of Good Pharmacovigilance Practice shall be inserted and read as follows:

   ""*Good Pharmacovigilance Practice" means the applicable principles and guidelines for good pharmacovigilance 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 European Medicines Agency's GVP modules I to XVI."*

4. A new definition of Technology Transfer Plan shall be inserted and read as follows:

   ""*Technology Transfer Plan" means: the plan mutually agreed and signed by the Parties for the transfer of Ascendis Technical Information from Ascendis to Licensee to the extent necessary to permit Licensee to Manufacture Licensed Products within the Territory. Such Technology Transfer Plan shall include (without limitation): (i) [***]."* All reasonable costs in accordance with the budget set forth in the technology Transfer Plan shall be covered by Licensee (including [***], all as agreed by Licensee in the Technology Transfer Plan).

5. Clause 4.3 of the Agreement shall be deleted and replaced with the following:

   "The Licensee shall be solely responsible for any clinical trial activities carried out as part of its development and commercialisation activities in the Territory. For such clinical trials, Licensee shall coordinate with Ascendis so that clinical endpoints, inclusion and exclusion criteria for the clinical trial are aligned with clinical trials conducted by Ascendis outside the Territory in similar indications, unless specific deviations are requested by the Regular Authority in the Territory, in which case the Parties shall in good faith discuss to propose an acceptable endpoint, inclusion or exclusion criteria with the Regulatory Authorities. However, if clinical trials are performed in the Territory in respect of the Licensed Product as part of a single global study to support Regulatory Approval in at least [***] in respect of the Licensed Product ("Multi-territory Study/ies"), then the performance of such Multi-territory Studies in the Territory shall be subject to the Parties' mutual agreement and the Parties' agreement in advance, in writing, as to their respective obligations in respect of any such Multi-territory Study, including (without limitation) the Parties' respective responsibilities for: [***]. If the Parties are unable to agree such matters in advance, the Licensee shall not participate in such Multi-territory Study."

6. Clause 4.4 of the Agreement shall be amended to read as follows:

"The Licensee shall use Diligent Efforts to develop and commercialise Licensed Product in the Field in the Territory. The Licensee shall ensure that such development and commercialisation of the Licensed Product are consistent with the Research and Technical Development Plan and Commercialisation Plan."

7. Clause 4.5 of the Agreement shall be amended to read as follows:

"Each Party shall conduct all development of Licensed Product in compliance with Applicable Laws, which shall include Good Laboratory Practice, Good Clinical Practice, Good Pharmacovigilance 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."

8. A new Clause 4.7 shall be inserted into the Agreement and read as follows:

"4.7 Joint Commercialisation Committee.

(A) Formation of the JCC. At least [***] prior to the first commercial sale of the Licensed Product in the Field in the Territory, the Parties will form a Joint Commercialisation Committee comprised of [***] (the "JCC").

(B) One representative of the Licensee at the JCC will be selected to act as the chairperson of the JCC. The JCC will meet at least [***] ([***]) times per year and such meetings may be conducted by videoconference, teleconference or in person, as agreed by the Parties. The JCC 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 JCC 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 JCC members, any needed changes discussed and final minutes agreed to and provided to each Party within [***] after each meeting unless otherwise agreed. A reasonable number of additional representatives of a Party may attend meetings of the JCC in a non-voting capacity. Each Party is responsible for its personnel and travel costs and expenses associated with attending meetings.

(C) JCC functions and powers. The responsibilities of the JCC will be as follows:

(1) encouraging and facilitating communication between the Parties with respect to the commercialisation of Licensed Product(s)) in the Field in the Territory;

(2) [***] the first Commercialisation Plan pursuant to Clause 4.8;

(3) [***] the Commercialisation Plan [***] and [***];

(4) exchanging information on the progress of the commercialisation of the Licensed Product in the Field in the Territory; and

(5) carrying out the other duties and responsibilities described for it in this Agreement.

(D) JCC Decision Making. All decisions of the JCC will be made by unanimous vote, with each of Ascendis and Licensee having one vote and the decisions will be recorded in the JCC minutes. If after reasonable discussion and consideration of each of the Parties' views on a particular matter before the JCC, the JCC is unable to reach a decision by unanimous vote on that matter, the following shall apply:

(a) the disputed matter shall [***];

(b) irrespective of above Clause 4.7 (D) (a), [***]. The JCC shall not have any authority other than that expressly set forth above and, specifically, shall have no authority: [***].

(E) Duration of the JCC. The JCC shall continue in full force and effect unless and until this Agreement expires or is terminated in accordance with Clause 18."

9. A new Clause 4.8 shall be inserted into the Agreement and read as follows:

"*4.8 Promptly following the establishment of the JCC, Licensee shall present to the JCC a plan setting out the commercial strategy for the commercialisation of the Licensed Products in the Field in the Territory including (without limitation) relating to branding, promotional materials, positioning in the market and medical affairs activities (including detailing), which with respect to content may not be inconsistent with the commercial strategy for the commercialisation of the Licensed Products in the Field outside the Territory) (the "Commercialisation Plan"). Such plan shall be [***] the JCC [***] thereafter no later than [***] and the JCC [***]."*

10. A new Clause 4.9 shall be inserted into the Agreement and read as follows:

"Promotional materials:

(A) Promotional materials including pre-marketing medical information material for the Licensed Products for use in the Territory shall be developed by the Licensee, comply with Applicable Laws and Regulatory Approvals (including approved label of the Licensed Product), and be scientifically accurate and consistent with data generated for the Licensed Product inside and outside the Territory. Copies of such materials shall be archived by the Parties to the extent required by Applicable Laws

(B) The Licensee shall submit English translations of samples of all such promotional materials to Ascendis, in advance of being used, for Ascendis' review and comment. Ascendis shall provide any comment to Licensee in writing within [***] of receipt of such samples and Licensee shall consider such comments in good faith and incorporate such comments.

(C) *The Licensee shall incorporate comments provided by Ascendis pursuant to above subsection 4.9 (B) to the extent they correct any scientific inaccuracy and / or correct any statements that are in contrast to any accurate statement regarding the Licensed Product used outside the Territory..”*

11. Clause 5.2(B) of the Agreement shall be amended to read as follows:

“*conduct all relevant packaging and distribution in accordance with Applicable Laws, which shall include Good Manufacturing Practice and Good Distribution Practice, in each case, to the extent applicable. In addition, Ascendis shall provide Licensee with written instructions in advance as to the best practice for handling and storing the Licensed Product and Licensee shall follow such instructions.”*

12. A new Clause 5.3 shall be inserted into the Agreement and read as follows:

“5.3 ***Technology Transfer***

5.3(A) If Licensee wishes to Manufacture Licensed Product in the Territory (including the TransCon [***], TransCon [***] or any other component which is proprietary to Ascendis or its CMO’s and necessary for the manufacture of the Licensed Product, but excluding the TransCon [***]) by itself or (subject to prior approval in writing by Ascendis, not to be unreasonably withheld, delayed or conditioned) via its subcontractors, it shall notify Ascendis of the same in writing, and the Parties shall cooperate in good faith to agree on a Technology Transfer Plan to implement the transfer of such Ascendis Technical Information (after relevant approval from affected CMO’s) to the extent necessary to permit Licensee to Manufacture the Licensed Products in the Territory. The Licensee shall be responsible for the following:

(a) the Manufacture of the Licensed Products by Licensee shall comply with standards required by the FDA and the European Medicines Agency, any International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (“ICH”) guidance, and Good Manufacturing Practice; and audited by Ascendis; and

(b) the Manufacturing process used following any technology transfer pursuant to this Clause 5.3 shall be, unless otherwise agreed to by Ascendis, identical or comparable (or modified solely to the extent necessary to meet local regulatory requirements) to the Manufacturing process used outside the Territory immediately prior to such technology transfer; and

(c) the Licensed Product manufactured by Licensee following a technology transfer shall be comparable to Licensed Product manufactured by Ascendis as determined in accordance with relevant guidelines issued by FDA and EMA. Licensee shall document in writing such comparability to Ascendis prior to any clinical or commercial use of Licensed Product by Licensee.

Licensee acknowledges and agrees that any such technology transfer may be subject to the consent of Ascendis' contract manufacturer(s) and any conditions and/or fees imposed by such contract manufacturer(s) in respect of the same. Ascendis shall seek the consent of such contract manufacturer(s) acting in good faith, provided that if such consent is not obtained, no transfer shall occur in respect of the activities performed by such contract manufacturer(s).

Promptly following the Parties agreeing to the content of the Technology Transfer Plan, the Parties shall perform the transfer from Ascendis or its contract manufacturer to Licensee (or its subcontractor if approved in writing by Ascendis) of the Ascendis Technical Information necessary to permit Licensee to Manufacture the Licensed Products in the Territory, in accordance with the relevant Technology Transfer Plan. Each Party shall use reasonable efforts to complete the tasks assigned to such Party under the Technology Transfer Plan in a timely manner and in accordance with the Technology Transfer Plan. Each Party shall designate qualified personnel having the necessary skill, expertise, and experience to facilitate such technology transfer and who shall be responsible for coordinating the technology transfer activities under the Technology Transfer Plan. Each Party shall cooperate with the other Party in such other Party's conduct of technology transfer activities under the Technology Transfer Plan. For the avoidance of doubt, such technology transfer shall not result in any change in the ownership or Control of any of the Ascendis Patents, Ascendis Technical Information, Ascendis Platform Technology, Ascendis Program IP or Joint Program IP, and all Technical Information so transferred to the Licensee for the Manufacture of Licensed Products constitutes Ascendis' Confidential Information. As between the Parties, Licensee shall be solely responsibility for obtaining and maintaining and shall own all Regulatory Approvals for its (or its subcontractor's) manufacture of Licensed Product from Regulatory Authorities in each of the jurisdictions in the Territory in the Field, and associated costs.

5.3(C) Licensee shall pay Ascendis' FTE Costs and travel costs incurred in the performance of the Technology Transfer Plan and all costs of any materials transferred to Licensee, in each case in accordance with the Technology Transfer Plan, subject to receipt of an invoice from Ascendis for such amounts. Licensee shall further pay any reasonable contract manufacturer's fees in connection with such technology transfer that Licensee agreed to pay as part of the Technology Transfer Plan. All other costs and expenses incurred by either Party in connection with the performance of the Technology Transfer Plan shall be borne by the incurring Party.

5.3(D) If, at any time after such technology transfer, the Manufacture of the Licensed Product by Licensee (or its subcontractors) fails to comply with Applicable Laws or the requirements set out in Clause 5.3(A)(a) – (c), then the Parties shall promptly confer and discuss an appropriate plan to remedy such failure for the future Manufacture of Licensed Product by Licensee (or its subcontractors)."

13. Clause 6.4 shall be amended to read as follows:

"6.4 The Licensee undertakes to comply, and to procure that its Sub-Licensees and contractors comply, with all requirements of Regulatory Authorities, Applicable Laws, which shall include Good Laboratory Practice, Good Manufacturing Practice, Good Distribution Practice and Good Pharmacovigilance Practice, in each case to the extent applicable."

14. Clause 6.5 shall be amended to read as follows:

"Ascendis shall provide assistance and information as reasonably requested by the Licensee in support of such regulatory activities, [***]. In addition to [***], Licensee shall bear the cost for any additional services conducted by the Ascendis Alliance Manager for the Licensee that is not already reimbursed by Licensee otherwise (e.g., reimbursed as part of the research, development or regulatory assistance), [***], provided that the Parties shall mutually agree upon the scope and time to be spent on such additional services prior to the Ascendis Alliance Manager conducting any such services."

15. Clause 8 shall be amended to read as follows:

"Each Party will maintain complete and accurate books, records and accounts in connection with its performance of this Agreement (including, without limitation, those used for the determination of any payment obligations under this Agreement). Such 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 retain such books, records and accounts for an additional [***] ([***]) years if reasonably available and required by the applicable tax authority. During the term of the Agreement and for a period of [***] thereafter, each Party, its Affiliates and/or their nominee may review and inspect such books, records, and accounts for the sole purpose of determining such other Party's compliance with this Agreement (including, without limitation, compliance with Clauses 4, 5, 6, 7, 9 and 10). Such review and inspection shall not take place more than [***] and shall be subject to the inspecting Party giving the other Party reasonable advance notice of such review and inspection and such review and inspection shall take place during normal business hours at a mutually agreed upon time (such agreement not to be unreasonably withheld, delayed or conditioned). The inspecting Party shall bear its own expenses, and the other Party shall reasonably cooperate with the inspecting Party, its Affiliates and/or nominee, in connection with any inspection. To the extent that any significant deficiencies are identified as the result of such inspection, the inspected Party shall take all reasonable corrective measures to remedy any such significant deficiencies. For clarity, any review or inspection pursuant to this Clause 8 shall be subject to the terms of Clause 10 and this Clause 8 shall survive the termination or expiry of this Agreement for [***]."

16. A new Clause 9.3 shall be inserted into the Agreement and read as follows:

"9.3 Each Party shall perform all pharmacovigilance in respect of the Licensed Product in compliance with Applicable Laws, which shall include Good Pharmacovigilance Practice to the extent applicable. As soon as practicable after the date of this letter, the Parties shall negotiate in good faith and enter into a pharmacovigilance agreement governing the pharmacovigilance activities of the Parties with respect to the Licensed Product."

17. This letter, once executed by both Parties, shall be deemed incorporated into the Agreement and all terms and conditions of the Agreement (including without limitation Clauses 1, 15, 18 (where Clauses 4.9 (A) and (C), 5.3(D), 6.4 and Clause 8 shall be added to the list of material obligations under Clause 18.2(b)), 19, 20 and 21), unless expressly modified in this letter, shall apply.

[***] 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.

VISEN Pharmaceuticals
P.O. Box 472
2nd Floor, Harbour Place
103 South Church Street
George Town, Grand Cayman KY1-1106
Cayman Islands

Attention: [***]

4 January, 2021

Amendment to the Exclusive Licence Agreement between Ascendis Pharma Bone Diseases A/S and Visen Pharmaceuticals dated 7 November 2018 (the "Agreement")

Dear Sirs or Madams

Further to the Parties' recent discussions regarding the Agreement, and in consideration of the Series B financing and the promises and mutual covenants set forth in this letter (including the appendix to this letter), we now wish to amend the Agreement as set out in the appendix to this letter.

These amendments shall take effect on and from the closing of the Series B financing. For the avoidance of doubt, all capitalised terms shall have the meaning given to them in the Agreement unless separately defined in this letter.

We confirm that all other terms and conditions of the Agreement remain unchanged and continue in full force and effect.

Please confirm your acceptance to these terms by countersigning this letter and the enclosed copy of this letter and returning the copy to us at [***] marked for the attention of [***], as soon as possible and, in any event, by 4 January 2021.

Yours faithfully

/s/ Jan Møller Mikkelsen
Jan Møller Mikkelsen, CEO

/s/ Michael Wolff Jensen
Michael Wolff Jensen, Chairman of the board of directors

for and on behalf of **Ascendis Pharma Bone Diseases A/S**

Accepted and agreed:

/s/ [***]

[***], Director 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.

Appendix : Amendments

1. A new definition of Ascendis Alliance Manager shall be inserted and read as follows:

   "*Ascendis Alliance Manager" means an FTE individual designated by Ascendis to ensure communication and alignment between Ascendis and Licensee regarding activities carried out by either Party under this Agreement. The annual FTE rate of such Ascendis Alliance Manager shall be EUR [***].*"

2. A new definition of Commercialisation Plan shall be inserted and read as follows:

   ""*Commercialisation Plan" has the meaning ascribed to it in Clause 4.8."*

3. A new definition of Good Pharmacovigilance Practice shall be inserted and read as follows:

   ""*Good Pharmacovigilance Practice" means the applicable principles and guidelines for good pharmacovigilance 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 European Medicines Agency's GVP modules I to XVI."*

4. A new definition of Technology Transfer Plan shall be inserted and read as follows:

   ""*Technology Transfer Plan" means: the plan mutually agreed and signed by the Parties for the transfer of Ascendis Technical Information from Ascendis to Licensee to the extent necessary to permit Licensee to Manufacture Licensed Products within the Territory. Such Technology Transfer Plan shall include (without limitation): (i) [***]."* All reasonable costs in accordance with the budget set forth in the technology Transfer Plan shall be covered by Licensee (including [***], all as agreed by Licensee in the Technology Transfer Plan).

5. Clause 4.3 of the Agreement shall be deleted and replaced with the following:

   "*The Licensee shall be solely responsible for any clinical trial activities carried out as part of its development and commercialisation activities in the Territory. For such clinical trials, Licensee shall coordinate with Ascendis so that clinical endpoints, inclusion and exclusion criteria for the clinical trial are aligned with clinical trials conducted by Ascendis outside the Territory in similar indications, unless specific deviations are requested by the Regular Authority in the Territory, in which case the Parties shall in good faith discuss to propose an acceptable endpoint, inclusion or exclusion criteria with the Regulatory Authorities. However, if clinical trials are performed in the Territory in respect of the Licensed Product as part of a single global study to support Regulatory Approval in at least [***] in respect of the Licensed Product ("Multi-territory Study/ies"), then the performance of such Multi-territory Studies in the Territory shall be subject to the Parties' mutual agreement and the Parties' agreement in advance, in writing, as to their respective obligations in respect of any such Multi-territory Study, including (without limitation) the Parties' respective responsibilities for: [***] If the Parties are unable to agree such matters in advance, the Licensee shall not participate in such Multi-territory Study."*

6. Clause 4.4 of the Agreement shall be amended to read as follows:

"The Licensee shall use Diligent Efforts to develop and commercialise Licensed Product in the Field in the Territory. The Licensee shall ensure that such development and commercialisation of the Licensed Product are consistent with the Research and Technical Development Plan and Commercialisation Plan."

7. Clause 4.5 of the Agreement shall be amended to read as follows:

"Each Party shall conduct all development of Licensed Product in compliance with Applicable Laws, which shall include Good Laboratory Practice, Good Clinical Practice, Good Pharmacovigilance 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."

8. A new Clause 4.7 shall be inserted into the Agreement and read as follows:

"*4.7 Joint Commercialisation Committee.*

(A) Formation of the JCC. At least [***] prior to the first commercial sale of the Licensed Product in the Field in the Territory, the Parties will form a Joint Commercialisation Committee comprised of [***] (the "JCC").

(B) One representative of the Licensee at the JCC will be selected to act as the chairperson of the JCC. The JCC will meet at least [***] ([***]) times per year and such meetings may be conducted by videoconference, teleconference or in person, as agreed by the Parties. The JCC 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 JCC 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 JCC members, any needed changes discussed and final minutes agreed to and provided to each Party within [***] after each meeting unless otherwise agreed. A reasonable number of additional representatives of a Party may attend meetings of the JCC in a non-voting capacity. Each Party is responsible for its personnel and travel costs and expenses associated with attending meetings.

(C) JCC functions and powers. The responsibilities of the JCC will be as follows:

(1) encouraging and facilitating communication between the Parties with respect to the commercialisation of Licensed Product(s)) in the Field in the Territory;

(2) [***] the first Commercialisation Plan pursuant to Clause 4.8;

(3) [***] the Commercialisation Plan [***] and [***];

(4) exchanging information on the progress of the commercialisation of the Licensed Product in the Field in the Territory; and

(5) carrying out the other duties and responsibilities described for it in this Agreement.

(D) JCC Decision Making. All decisions of the JCC will be made by unanimous vote, with each of Ascendis and Licensee having one vote and the decisions will be recorded in the JCC minutes. If after reasonable discussion and consideration of each of the Parties' views on a particular matter before the JCC, the JCC is unable to reach a decision by unanimous vote on that matter, the following shall apply:

(a) the disputed matter shall be [***];

(b) irrespective of above Clause 4.7 (D) (a), [***]. The JCC shall not have any authority other than that expressly set forth above and, specifically, shall have no authority: [***]

(E) Duration of the JCC. The JCC shall continue in full force and effect unless and until this Agreement expires or is terminated in accordance with Clause 18."

9. A new Clause 4.8 shall be inserted into the Agreement and read as follows:

"*4.8 Promptly following the establishment of the JCC, Licensee shall present to the JCC a plan setting out the commercial strategy for the commercialisation of the Licensed Products in the Field in the Territory including (without limitation) relating to branding, promotional materials, positioning in the market and medical affairs activities (including detailing), which with respect to content may not be inconsistent with the commercial strategy for the commercialisation of the Licensed Products in the Field outside the Territory) (the "Commercialisation Plan"). Such plan shall be [***] the JCC [***] thereafter no later than [***] and the JCC [***]."*

10. A new Clause 4.9 shall be inserted into the Agreement and read as follows:

"Promotional materials:

(A) *Promotional materials including pre-marketing medical information material for the Licensed Products for use in the Territory shall be developed by the Licensee, comply with Applicable Laws and Regulatory Approvals (including approved label of the Licensed Product), and be scientifically accurate and consistent with data generated for the Licensed Product inside and outside the Territory. Copies of such materials shall be archived by the Parties to the extent required by Applicable Laws*

(B) *The Licensee shall submit English translations of samples of all such promotional materials to Ascendis, in advance of being used, for Ascendis' review and comment. Ascendis shall provide any comment to Licensee in writing within [***] of receipt of such samples and Licensee shall consider such comments in good faith and incorporate such comments.*

(C) *The Licensee shall incorporate comments provided by Ascendis pursuant to above subsection 4.9 (B) to the extent they correct any scientific inaccuracy and / or correct any statements that are in contrast to any accurate statement regarding the Licensed Product used outside the Territory..”*

11. Clause 5.2(B) of the Agreement shall be amended to read as follows:

“*conduct all relevant packaging and distribution in accordance with Applicable Laws, which shall include Good Manufacturing Practice and Good Distribution Practice, in each case, to the extent applicable. In addition, Ascendis shall provide Licensee with written instructions in advance as to the best practice for handling and storing the Licensed Product and Licensee shall follow such instructions.”*

12. A new Clause 5.3 shall be inserted into the Agreement and read as follows:

“5.3 ***Technology Transfer***

5.3(A) If Licensee wishes to Manufacture Licensed Product in the Territory (including the TransCon [***], TransCon [***] or any other component which is proprietary to Ascendis or its CMO's and necessary for the manufacture of the Licensed Product, but excluding the TransCon [***]) by itself or (subject to prior approval in writing by Ascendis, not to be unreasonably withheld, delayed or conditioned) via its subcontractors, it shall notify Ascendis of the same in writing, and the Parties shall cooperate in good faith to agree on a Technology Transfer Plan to implement the transfer of such Ascendis Technical Information (after relevant approval from affected CMO's) to the extent necessary to permit Licensee to Manufacture the Licensed Products in the Territory. The Licensee shall be responsible for the following:

(a) the Manufacture of the Licensed Products by Licensee shall comply with standards required by the FDA and the European Medicines Agency, any International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (“ICH”) guidance, and Good Manufacturing Practice; and audited by Ascendis; and

(b) the Manufacturing process used following any technology transfer pursuant to this Clause 5.3 shall be, unless otherwise agreed to by Ascendis, identical or comparable (or modified solely to the extent necessary to meet local regulatory requirements) to the Manufacturing process used outside the Territory immediately prior to such technology transfer; and

(c) the Licensed Product manufactured by Licensee following a technology transfer shall be comparable to Licensed Product manufactured by Ascendis as determined in accordance with relevant guidelines issued by FDA and EMA. Licensee shall document in writing such comparability to Ascendis prior to any clinical or commercial use of Licensed Product by Licensee.

Licensee acknowledges and agrees that any such technology transfer may be subject to the consent of Ascendis' contract manufacturer(s) and any conditions and/or fees imposed by such contract manufacturer(s) in respect of the same. Ascendis shall seek the consent of such contract manufacturer(s) acting in good faith, provided that if such consent is not obtained, no transfer shall occur in respect of the activities performed by such contract manufacturer(s).

Promptly following the Parties agreeing to the content of the Technology Transfer Plan, the Parties shall perform the transfer from Ascendis or its contract manufacturer to Licensee (or its subcontractor if approved in writing by Ascendis) of the Ascendis Technical Information necessary to permit Licensee to Manufacture the Licensed Products in the Territory, in accordance with the relevant Technology Transfer Plan. Each Party shall use reasonable efforts to complete the tasks assigned to such Party under the Technology Transfer Plan in a timely manner and in accordance with the Technology Transfer Plan. Each Party shall designate qualified personnel having the necessary skill, expertise, and experience to facilitate such technology transfer and who shall be responsible for coordinating the technology transfer activities under the Technology Transfer Plan. Each Party shall cooperate with the other Party in such other Party's conduct of technology transfer activities under the Technology Transfer Plan. For the avoidance of doubt, such technology transfer shall not result in any change in the ownership or Control of any of the Ascendis Patents, Ascendis Technical Information, Ascendis Platform Technology, Ascendis Program IP or Joint Program IP, and all Technical Information so transferred to the Licensee for the Manufacture of Licensed Products constitutes Ascendis' Confidential Information. As between the Parties, Licensee shall be solely responsibility for obtaining and maintaining and shall own all Regulatory Approvals for its (or its subcontractor's) manufacture of Licensed Product from Regulatory Authorities in each of the jurisdictions in the Territory in the Field, and associated costs.

5.3(C) Licensee shall pay Ascendis' FTE Costs and travel costs incurred in the performance of the Technology Transfer Plan and all costs of any materials transferred to Licensee, in each case in accordance with the Technology Transfer Plan, subject to receipt of an invoice from Ascendis for such amounts. Licensee shall further pay any reasonable contract manufacturer's fees in connection with such technology transfer that Licensee agreed to pay as part of the Technology Transfer Plan. All other costs and expenses incurred by either Party in connection with the performance of the Technology Transfer Plan shall be borne by the incurring Party.

5.3(D) If, at any time after such technology transfer, the Manufacture of the Licensed Product by Licensee (or its subcontractors) fails to comply with Applicable Laws or the requirements set out in Clause 5.3(A)(a) – (c), then the Parties shall promptly confer and discuss an appropriate plan to remedy such failure for the future Manufacture of Licensed Product by Licensee (or its subcontractors)."

[***] 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.

13. Clause 6.4 shall be amended to read as follows:

"6.4 The Licensee undertakes to comply, and to procure that its Sub-Licensees and contractors comply, with all requirements of Regulatory Authorities, Applicable Laws, which shall include Good Laboratory Practice, Good Manufacturing Practice, Good Distribution Practice and Good Pharmacovigilance Practice, in each case to the extent applicable."

14. Clause 6.5 shall be amended to read as follows:

"Ascendis shall provide assistance and information as reasonably requested by the Licensee in support of such regulatory activities, [***]. In addition to [***], Licensee shall bear the cost for any additional services conducted by the Ascendis Alliance Manager for the Licensee that is not already reimbursed by Licensee otherwise (e.g., reimbursed as part of the research, development or regulatory assistance), [***], provided that the Parties shall mutually agree upon the scope and time to be spent on such additional services prior to the Ascendis Alliance Manager conducting any such services."

15. Clause 8 shall be amended to read as follows:

"Each Party will maintain complete and accurate books, records and accounts in connection with its performance of this Agreement (including, without limitation, those used for the determination of any payment obligations under this Agreement). Such 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 retain such books, records and accounts for an additional [***] ([***]) years if reasonably available and required by the applicable tax authority. During the term of the Agreement and for a period of [***] thereafter, each Party, its Affiliates and/or their nominee may review and inspect such books, records, and accounts for the sole purpose of determining such other Party's compliance with this Agreement (including, without limitation, compliance with Clauses 4, 5, 6, 7, 9 and 10). Such review and inspection shall not take place more than [***] and shall be subject to the inspecting Party giving the other Party reasonable advance notice of such review and inspection and such review and inspection shall take place during normal business hours at a mutually agreed upon time (such agreement not to be unreasonably withheld, delayed or conditioned). The inspecting Party shall bear its own expenses, and the other Party shall reasonably cooperate with the inspecting Party, its Affiliates and/or nominee, in connection with any inspection. To the extent that any significant deficiencies are identified as the result of such inspection, the inspected Party shall take all reasonable corrective measures to remedy any such significant deficiencies. For clarity, any review or inspection pursuant to this Clause 8 shall be subject to the terms of Clause 10 and this Clause 8 shall survive the termination or expiry of this Agreement for [***]."

[***] 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.

16. A new Clause 9.3 shall be inserted into the Agreement and read as follows:

"9.3 Each Party shall perform all pharmacovigilance in respect of the Licensed Product in compliance with Applicable Laws, which shall include Good Pharmacovigilance Practice to the extent applicable. As soon as practicable after the date of this letter, the Parties shall negotiate in good faith and enter into a pharmacovigilance agreement governing the pharmacovigilance activities of the Parties with respect to the Licensed Product."

17. This letter, once executed by both Parties, shall be deemed incorporated into the Agreement and all terms and conditions of the Agreement (including without limitation Clauses 1, 15, 18 (where Clauses 4.9 (A) and (C), 5.3(D), 6.4 and Clause 8 shall be added to the list of material obligations under Clause 18.2(b)), 19, 20 and 21), unless expressly modified in this letter, shall apply.

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, 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
Ascendis Pharma Oncology Division 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: March 10, 2021

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: March 10, 2021

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, 2020, 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: March 10, 2021

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, 2020, 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: March 10, 2021

By: /s/ Scott T. Smith
Name: Scott T. Smith
Title: Chief Financial Officer and Principal Financial Officer

Exhibit 15.1

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 March 10, 2021, relating to the consolidated financial statements of Ascendis Pharma A/S and the effectiveness of Ascendis Pharma A/S's internal control over financial reporting appearing in this Annual Report on Form 20-F for the year ended December 31, 2020.

Deloitte Statsautoriseret Revisionspartnerselskab
CVR no. 33963556

/s/ Sumit Sudan
State Authorised Public Accountant

/s/ Lars Hansen
State Authorised Public Accountant

Copenhagen, Denmark

March 10, 2021