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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, 2015

OR

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

For the transition period from _____ to _____

OR

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

Date of event requiring this shell company report

Commission file number: 001-36815

Ascendis Pharma A/S

(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)

The Kingdom of Denmark
(Jurisdiction of incorporation or organization)

Tuborg Boulevard 5
DK-2900 Hellerup, Denmark
(Address of principal executive offices)

Jan Møller Mikkelsen
President and Chief Executive Officer
Tuborg Boulevard 5
DK-2900 Hellerup, Denmark
Telephone: +45 36 94 44 86
Fax: +45 36 94 40 10
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

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

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

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

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

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

25,128,242 ordinary shares
(as of December 31, 2015)

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

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

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

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

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

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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 financial statements are presented in Euros except where otherwise indicated, and are prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). Our consolidated financial statements are presented in euros. All references in this annual report to "Dollars" and "$" are to US Dollars, and all references to "Euro" or "€" are to European Union Euro. Throughout this annual report, references to ADSs mean ADSs or ordinary shares represented by ADSs, as the case may be. All share and per share data in this annual report, including those relating to the warrants, gives retroactive effect to the bonus issue of shares in the ratio of 3:1 of the Company's authorized, issued and outstanding shares, which was resolved on January 13, 2015.

Special Note Regarding Forward-Looking Statements

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than present and historical facts and conditions contained in this annual report, including statements regarding our future results of operations and financial positions, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this annual report, the words "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 of or indicate future events and future trends, or the negative of these terms or other comparable terminology identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the timing of a planned Phase 3 study of once-weekly TransCon human growth hormone;
- our receipt of future milestone payments from our collaboration partners, and the expected timing of such payments;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- our expectations regarding the potential advantages of our prodrug 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 technology and file Investigational New Drug Applications for such product candidates;
- our expectations with regard to the ability to seek expedited regulatory approval pathways for our product candidates, including the ability to rely on the parent drug's clinical and safety data with regard to our prodrug product candidates;
- our expectations with regard to our current and future collaboration partners to pursue the development of our prodrug product candidates;
- our development plans with respect to our product candidates;

- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;
- the timing or likelihood of regulatory filings and approvals for our product candidates;
- the commercialization of our product candidates;
- our commercialization, marketing and manufacturing capabilities;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012;
- our financial performance; and
- developments and projections relating to our competitors and our industry.

You should refer to the section of this annual report titled "Item 3.D—Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this annual report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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. We qualify all of our forward-looking statements by these cautionary statements.

PART I

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

Not applicable.

Item 2 ***Offer Statistics and Expected Timetable***

Not applicable.

Item 3 ***Key Information***

A. Selected Financial Data

The selected consolidated financial data as of December 31, 2015 and 2014 and for each of the years ended December 31, 2015, 2014 and 2013 have been derived from our audited consolidated financial statements and notes thereto set forth in Item 18 of this annual report. The selected consolidated financial data for the year ended December 31, 2012 is derived from the audited consolidated financial statements not appearing in this annual report.

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

	Years Ended December 31,			
(EUR'000, except share and per share data)	**2015**	**2014**	**2013**	**2012**
Revenue	8,118	13,983	20,408	15,583
Research and development costs	(40,528)	(19,698)	(12,713)	(11,380)
General and administrative expenses	(9,415)	(6,274)	(2,416)	(2,690)
Operating profit / (loss)	**(41,825)**	**(11,989)**	**5,279**	**1,513**
Finance income	11,048	1,877	158	4
Finance expenses	(2,797)	(228)	(732)	(232)
Profit / (loss) before tax	**(33,574)**	**(10,340)**	**4,705**	**1,285**
Tax on profit / (loss) for the year	652	682	(626)	(35)
Net profit / (loss) for the year	**(32,922)**	**(9,658)**	**4,079**	**1,250**
Other comprehensive income				
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translating foreign operations	(14)	(14)	(6)	(51)
Other comprehensive income / (loss) for the year, net of tax	**(14)**	**(14)**	**(6)**	**(51)**
Total comprehensive income / (loss) for the year, net of tax	**(32,936)**	**(9,672)**	**4,073**	**1,199**
Profit / (loss) for the year attributable to owners of the Company	(32,922)	(9,658)	4,079	1,250
Total comprehensive income / (loss) for the year attributable to owners of the Company	(32,936)	(9,672)	4,073	1,199
	EUR	**EUR**	**EUR**	**EUR**
Basic earnings per share	(1.39)	(0.85)	0.38	.012
Diluted earnings per share	(1.39)	(0.85)	0.32	0.10
Weighted average number of shares used for calculation (basic)	23,766,783	11,406,929	10,801,948	10,801,948
Weighted average number of shares used for calculation (diluted)	23,766,783	11,406,929	12,825,908	12,055,996

The total number of ordinary shares outstanding as of December 31, 2015, 2014, 2013 and 2012 was 25,128,242, 16,935,780, 10,801,948 and 10,801,948, respectively. The registered share capital as of December 31, 2015, 2014, 2013 and 2012 was DKK 25,128,242, DKK 4,233,945, DKK 2,700,487 and DKK 2,700,487, respectively.

Selected Consolidated Statement of Financial Position Data:

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

	As of December 31,			
(€ '000)	**2015**	**2014**	**2013**	**2012**
Cash and cash equivalents	119,649	50,167	19,430	14,535
Total assets	131,774	58,671	26,700	25,405
Total liabilities	11,445	12,861	20,399	23,849
Retained earnings/(accumulated deficit)	111,277	39,559	2,134	(1,946)
Total equity	120,329	45,810	6,301	1,556

Selected Consolidated Cash Flow Statement Data:

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

	Year Ended December 31,			
(EUR'000)	**2015**	**2014**	**2013**	**2012**
Cash flows from/(used in) operating activities	(43,466)	(18,403)	6,310	(652)
Cash flows used in investing activities	(1,039)	(405)	(1,195)	(291)
Cash flows from /(used in) financing activities	105,742	47,907	(220)	(205)

Exchange Rate Information

Our business is primarily conducted in the European Union, and we maintain our books and records in euros. We have presented results of operations in euros. In this annual report, financial figures included in or extracted from our audited consolidated financial statements have been translated in accordance with the guidelines under IFRS. For convenience of the reader, this annual report also includes other translations from euros to U.S. dollars and U.S. dollars to euros. Unless specified as of a specific date, or otherwise indicated, translations from euros to U.S. dollars and from U.S. dollars to euros were made at a rate of €0.915 to $1.00, the official exchange rate quoted by the European Central Bank at the close of business on December 31, 2015. As of April 14, 2016, the official exchange rate of euros to U.S. dollars was €0.89 to $1.00. Such U.S. dollar amounts are not necessarily indicative of the actual amounts of U.S. dollars which could have been actually purchased on exchange of euro on the dates indicated. The rates set forth below are provided solely for your convenience and may differ from the actual rates used in the preparation of our consolidated financial statements and other financial data included in this annual report.

The following table presents information on the exchange rates between the euro and the U.S. dollar for the periods indicated:

		Average		
	Period end	**for period**	**Low**	**High**
	(€ per U.S. dollar)			
Year Ended December 31				
2011	0.773	0.718	0.672	0.776
2012	0.758	0.778	0.743	0.827
2013	0.725	0.753	0.724	0.783
2014	0.824	0.757	0.717	0.824
2015	0.915	0.922	0.827	0.954
Month Ended				
September 30, 2015	0.895	0.890	0.877	0.899
October 31, 2015	0.910	0.891	0.871	0.915
November 30, 2015	0.945	0.933	0.910	0.945
December 31, 2015	0.915	0.922	0.908	0.946
January 31, 2016	0.914	0.921	0.914	0.930
February 29, 2016	0.915	0.901	0.883	0.924
March 31, 2016	0.882	0.898	0.882	0.920
April 2016 (through April 14, 2016)	0.888	0.879	0.786	0.888

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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

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

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

We are a clinical stage biopharmaceutical company applying our TransCon technology to develop long-acting prodrug therapies with several product candidates in clinical and preclinical development. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused substantially all of our efforts on our research and development activities and, in particular, developing our lead product candidate, TransCon hGH, and our proprietary TransCon technology. We have only a limited operating history upon which our shareholders and ADS holders can evaluate our business and prospects. Our revenue has been primarily generated through collaboration agreements under which we have received up-front technology licensing fees, payments for the sale of certain intellectual property rights and payments we receive for services rendered to our collaboration partners and other biopharmaceutical companies. Revenue generated from existing or new collaborations may fluctuate significantly over time. Accordingly, going forward, we may incur significant losses from our operations. We had a net loss of €32.9 million during the year ended December 31, 2015 and a net loss of €9.7 million during the year ended December 31, 2014. Our total equity was €120.3 million as of December 31, 2015 compared to €45.8 million as of December 31, 2014. 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 European Medicines Agency, or EMA, the U.S. Food and Drug Administration, or FDA, 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, product discovery and development efforts and operate as a public company. Even if we receive milestone payments from our current or future collaboration partners, we may incur substantial operating losses for the foreseeable future as we execute our operating plan. Additionally, we cannot be certain that we will receive any potential milestones under our agreements with our collaboration partners. For a discussion of the risks associated with our preclinical and clinical development programs with, and potential for milestone and other payments from, our collaboration partners, see "—Risks Related to Our Business."

Even if we receive milestone payments or royalty payments from our current or future collaboration partners, we may not be able to achieve or sustain profitability. For example, our receipt of milestone payments or up-front payments from our current and potential collaboration partners may not result in the recognition of revenue in the period received, as we may be required to defer the revenue recognition of such payments over time, and depending upon such requirements and the period of recognition, we may still incur losses even after the receipt of

such payments. Therefore, we expect that we may incur significant losses in the future. Possible future losses would have an adverse effect on our shareholders' equity. Further, the net losses or net income we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a reliable indication of our future performance.

We have never generated any revenue from product sales.

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

- completing research and preclinical and clinical development of our product candidates;
- on our own, or together with our strategic collaboration partners, obtaining regulatory approvals for our product candidates;
- negotiating favorable terms of and entering into collaboration, licensing or other arrangements;
- the ability of our collaboration partners to successfully commercialize and/or our ability to commercialize or co-promote our product candidates;
- developing a sustainable and scalable manufacturing process for any of our approved product candidates and establishing and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate, in amount and quality, products to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates, if approved, as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring, in-licensing and/or developing new product candidates;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how, and our ability to develop, manufacture and commercialize our product candidates and products without infringing intellectual property rights of others; and
- attracting, hiring, and retaining qualified personnel.

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

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

Since our inception, most of our resources have been dedicated to our research and development activities and, in particular, developing our proprietary TransCon technology and our most advanced product candidates. In February 2015, we received $111.5 million (€101.4 million) in net proceeds from our initial public offering after deducting the underwriting commission and offering expenses payable by us and as of December 31, 2015, we had cash and cash equivalents of €119.6 million. We believe that we will continue to expend substantial resources for the foreseeable future, including costs associated with research and development, conducting preclinical studies, clinical trials, obtaining regulatory approvals and, eventually, sales and marketing if any of our product candidates is approved. Because the outcome of any clinical trial and/or regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts of additional financing necessary to successfully complete the development, regulatory approval process and commercialization or co-promotion of any of our product candidates.

Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2015 will allow us to fund our operating plan through at least the 12 months from the date of this annual report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including, but not limited to:

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the achievement of development, regulatory and commercial milestones resulting in the payment to us from our collaboration partners of contractual milestone payments and the timing of receipt of such payments, if any;
- 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;
- our progress and the progress of our collaboration partners 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;
- the manufacturing, selling and marketing costs associated with product candidates, including the cost and timing of building our sales and marketing capabilities;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the sales price and the availability of adequate third-party coverage and reimbursement for our product candidates;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the number and scope of preclinical and discovery programs that we decide to pursue or initiate;
- the potential acquisition and in-licensing of other technologies, products or assets;
- the time and cost necessary to respond to technological and market developments; and

- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation, including costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of our product candidates.

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

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

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, the ownership interest of our shareholders and ADS holders would be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our shareholders and ADS holders. Such financing may result in dilution to holders of shares or ADSs, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic partnerships with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Risks Related to Our Business

We are substantially dependent on the success of our most advanced 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 most advanced product candidates utilizing our proprietary TransCon technology. In particular, we are currently planning to initiate a Phase 3 trial for TransCon hGH in pediatric GHD patients in mid-2016. Our near-term prospects, including our ability to finance our operations through the receipt of milestone payments and potential up-front licensing payments and generate revenue from product sales, will depend heavily on our successful development and commercialization of our most advanced product candidates, if approved. The clinical and commercial success of our most advanced product candidates and our TransCon technology will depend on a number of factors, including the following:

- the outcome and timely initiation and execution of the planned Phase 3 clinical trial of TransCon hGH, which will depend substantially upon the satisfactory performance of third-party contractors;
- our ability and that of our collaboration partners to establish commercial-scale manufacturing processes for our most advanced product candidates, which has not yet been demonstrated;
- whether our most advanced product candidates' safety, tolerability and efficacy profiles will be satisfactory to the EMA, the FDA and similar regulatory authorities to warrant marketing approval;
- whether the EMA, the FDA or similar regulatory authorities require additional clinical trials prior to approval to market our most advanced product candidates;
- the prevalence and severity of adverse side effects of our most advanced product candidates;

- the timely receipt of necessary marketing approvals from the EMA, the FDA and similar regulatory authorities;
- our ability and that of our collaboration partners to successfully commercialize our most advanced 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 most advanced product candidates as safe and effective 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 most advanced product candidates by third-party payors;
- the effectiveness of our collaboration partners' marketing, sales and distribution strategies and operations;
- our ability and that of our collaboration partners, or any third-party manufacturer we or our collaborators contract with, to manufacture supplies of our most advanced 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 most advanced 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 most advanced product candidates following approval, if approved.

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

Additionally, our clinical and regulatory approval plan for TransCon hGH is to conduct a single Phase 3 trial in a pediatric population with a primary endpoint of mean height velocity measured over 12 months. It is possible, however, that because TransCon hGH is a prodrug form of hGH that it is a new molecular entity, we will not be able to use this clinical and regulatory approval strategy. If we have to conduct additional or different trials, this could increase the amount of time and expense required for regulatory approval of TransCon hGH, if approved at all. In July 2015, we reported positive top-line six-month height velocity data from 53 patients treated in our Phase 2 TransCon hGH clinical study in pediatric growth hormone deficient patients. If the six-month mean height velocities that we observed for TransCon hGH in the Phase 2 pediatric study do not correlate to twelve month mean height velocities that we ultimately observe in the Phase 3 clinical study that we plan to conduct, TransCon hGH may not achieve the required primary endpoint in the Phase 3 clinical trial, and therefore may not receive regulatory approval.

Accordingly, we cannot be certain that our most advanced product candidates will ever be approved or successfully commercialized, or that we will ever generate revenue from sales of such product candidates. If we and our collaboration partners are not successful in completing the development of, obtaining approval for, and commercializing our most advanced product candidates, or are significantly delayed in doing so, our business will be harmed.

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

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we, or our current or future collaboration partners, must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process; the results of preclinical and clinical studies of our product candidates may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in preclinical and clinical studies for TransCon hGH do not ensure that the planned Phase 3 clinical trial, or other clinical trials, will demonstrate similar results. 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 or to be able to use an expedited regulatory pathway for approval of our product candidates.

We may experience delays in our planned Phase 3 trial or other trials, and we do not know whether future clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delay or failure to:

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

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

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

Further, we are planning to conduct our Phase 3 pediatric study of TransCon hGH across many clinical sites globally, including sites located across Europe and North America. Conducting clinical trials in foreign countries presents additional risks that may delay completion of clinical trials. These risks include the failure of physicians or enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. In addition, the EMA or the FDA may determine that the clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product candidate when administered in EEA or U.S. patients, and are thus not supportive of an application for a marketing authorization in the EEA or of an NDA 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 proceed with filing an NDA in the United States or a marketing authorization application in the EEA. The EMA or the FDA may even require conducting additional clinical trials in the EEA or the United States, respectively.

If there are delays in the completion of, or termination of, any clinical trial of our product candidates or if we are required to conduct additional clinical trials in addition to those we have currently planned, the commercial prospects of our product candidates may be harmed, and our ability to generate revenue from product sales from any of these product candidates will be delayed. In addition, any delays in completing the clinical trials will increase costs, slow down our product candidate development and approval process and jeopardize the ability to commence product sales and generate revenue from product sales. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

We rely on our collaboration partners to conduct clinical studies of our collaboration product candidates. We have existing collaborations with Sanofi and Genentech. Under these collaborations, we granted Sanofi and Genentech worldwide licenses to develop certain collaboration product candidates in the fields of diabetes (unspecified TransCon Peptides) and ophthalmology (TransCon Ranibizumab), respectively. We may also enter into collaboration agreements with other parties in the future relating to our other product candidates. Under our existing collaboration agreements, our collaboration partners are responsible for completing all preclinical and clinical development and obtaining and maintaining regulatory approval for the applicable product candidates from the EMA, the FDA and similar regulatory authorities. Ultimately, if such product candidates are advanced through clinical trials and receive marketing approval from the EMA, the FDA or similar regulatory authorities, such collaboration partners will be responsible for commercialization of these collaboration products. The potential for us to obtain future development milestone payments and, ultimately, generate revenue from royalties on sales of such collaboration products depends entirely on successful development, regulatory approval, marketing and commercialization by our collaboration partners.

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

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, manufacture, 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 may fail to develop a commercially viable formulation or manufacturing process for our product candidates, and may fail to manufacture or supply sufficient drug substance for commercial use, if approved, which could result in lost revenue;
- our collaboration partners may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- if any of our agreements with our collaboration partners terminate, we will no longer have any rights to receive potential revenue under such agreement, in which case we would need to identify alternative means to continue the development, manufacture and commercialization of the affected product candidates, alone or with others;

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

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

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

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

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

We may form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to our independent programs that we believe will complement or augment our existing business. We have historically engaged, and intend to continue to engage, in partnering discussions with a range of biopharmaceutical companies and could enter into new collaborations at any time. 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, including that our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, and/or third parties may not view our product candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile. Even if we are successful in entering into a strategic alliance or license arrangement, there is no guarantee that the collaboration will be successful, or that any future collaboration partner will commit sufficient resources to the development, regulatory approval, and commercialization of our product candidates, or that such alliances will result in us achieving revenues that justify such transactions.

Our product candidates, other than TransCon hGH and TransCon Treprostinil, 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 technology, and to advance such product candidates through clinical development, either on our own or in conjunction with strategic collaboration partners. Other than TransCon hGH and TransCon Treprostinil, our current unlicensed product candidates are in various stages of preclinical development, and will require substantial preclinical and clinical development and testing, and eventually regulatory approval, prior to commercialization. TransCon hGH is our only unlicensed product candidate currently in active clinical development. TransCon Treprostinil has completed a Phase 1 clinical trial and is currently undergoing additional preclinical evaluation by us. Our other unlicensed product candidates are in preclinical development and may require significant time and additional research and development before we can file a Clinical Trial Application or IND 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 technology 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 technology may not be successful in identifying 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;
- the market for a product candidate may change during our program so that such a product may become financially unfeasible to continue to develop;
- a product candidate may be demonstrated to have harmful side effects or not to be effective, or otherwise not to meet other requirements for regulatory approval;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, or reimbursable by third-party payors, if applicable.

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

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

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

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

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

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

We do not 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 product 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 clinical indications for which the product is approved;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment and their willingness to pay for them;
- relative convenience and ease of administration of our products;
- the potential and perceived advantages of our product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the availability of supply of our products and their ability to meet market demand;
- marketing and distribution support for our product candidates;
- the quality of our relationships with patient advocacy groups; and
- coverage and reimbursement policies of government and other third-party payors.

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

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

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

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

- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or our collaboration partners, may be required to recall the product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof, including the imposition of a Risk Evaluation and Mitigation Strategies plan that may require creation of a Medication Guide outlining the risks of such side effects for distribution to patients, as well as elements to assure safe use of the product, such as a patient registry and training and certification of prescribers;
- we, or our collaboration partners, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

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

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

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

We are aware of several pharmaceutical and biopharmaceutical companies that have commenced clinical studies of products or have successfully commercialized products addressing areas that we are targeting. For example, several companies are developing long-acting products for the treatment of growth hormone deficiency, including Bioton S.A., Critical Pharmaceuticals, Ltd., Dong-A Pharmaceutical, GeneScience Pharmaceuticals Co., Ltd., Genexine Inc., Hanmi Pharmaceuticals Co., Ltd., Novo Nordisk A/S, OPKO Health, Inc. (in collaboration with Pfizer Inc.), Teva Pharmaceutical Industries Ltd. and Versartis, Inc. Other companies are developing or commercializing prostacyclin-based therapies to treat pulmonary arterial hypertension, or PAH, including Actelion Pharmaceuticals Ltd., GlaxoSmithKline LLC, Insmed Inc., and United Therapeutics Corporation, and many small and large biopharmaceutical companies are developing therapies for diabetes and ophthalmic indications. In addition to product-based competition, our TransCon technology faces 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 technology.

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

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

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

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

Many of our competitors have:

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

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

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

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

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

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

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

We apply our TransCon technology 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 TransCon technology with respect to safety and efficacy for long-term treatment in humans. The long-term safety and efficacy of our TransCon technology and the extended life in the body of our product candidates utilizing TransCon technology 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 technology, we may be unable to successfully develop or commercialize our product candidates.

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

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

We have limited clinical data on product candidates utilizing the TransCon technology platform 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 TransCon technology 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®, and Adynovate® and we are not aware of any evidence for PEG-related safety issues with PEGylated proteins in the clinic, health authorities, including the EMA, have historically posed general questions relating to the distribution, elimination, and the potential for PEG accumulation to pharmaceutical companies involved in the development of PEGylated drug products. If treatment with any of our product candidates in our clinical trials results in concerns about their safety or efficacy, we and our collaboration partners may be unable to successfully develop or commercialize any or all of our TransCon technology based product candidates or enter into collaborations with respect to our product candidates.

We have limited clinical data on TransCon hGH and TransCon Treprostinil to indicate whether they are safe or effective for long-term use in humans.

We have generated clinical data on six months of dosing with TransCon hGH, single-dose clinical data on TransCon Treprostinil, and no clinical data on any of our other product candidates that utilize the TransCon technology to extend their duration of action. It is unknown whether long-term repeated administration of TransCon hGH or TransCon Treprostinil could result in issues that may adversely affect safety. If extended treatment with TransCon hGH, TransCon Treprostinil, or any of our other product candidates, in our clinical trials, results in any safety or efficacy concerns, we may be unable to successfully develop or commercialize our product candidates or enter into collaborations with respect to our product candidates.

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

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

We currently do not have our own sales organization. In order to commercialize any of our product candidates, we or our collaboration partners must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we 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 marketing, 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 collaborate 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.

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

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

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

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

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

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

Under our agreements with our collaboration partners, the manufacturing of our collaboration product candidates are the responsibility of the applicable collaboration partner. We are entirely dependent on our collaboration partners for all aspects of the manufacturing and validation process, as well as providing all commercial supply of our collaboration product candidates. For additional information regarding the risks of our dependence on our collaboration partners, see the risk factors above "—We are substantially dependent on the success of our most advanced product candidates, which may not be successful in nonclinical studies or clinical trials, receive regulatory approval or be successfully commercialized" and "—We depend on collaboration partners to develop and conduct clinical studies with, obtain regulatory approvals for, and manufacture, market and sell our collaboration product candidates, and if such collaboration partners fail to perform as expected, or are unable to obtain the required regulatory approvals for such product candidates, the potential for us to generate future revenue from such product candidates would be significantly reduced and our business would be significantly harmed."

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

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. Any significant delay or discontinuation in the supply of such materials would delay completion of our clinical studies 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, 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 clinical studies, product testing, and potential regulatory approval of our product candidates, which could harm our business and results of operations.

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

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

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

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

It is generally necessary for us to secure certain levels of insurance as a condition for the conduct of clinical studies. We believe that our product liability insurance for clinical studies is sufficient to cover claims. We currently maintain liability insurance with certain specified coverage limits. We cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop. We currently carry product liability insurance covering use in our clinical trials in the amount of $8 million in the aggregate. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various, limits, exclusions and deductibles, and given these various limits, exclusions and deductibles, we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms.

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

As of December 31, 2015, we had 78 full-time employees. As we and/or our collaboration partners advance our product candidates through the development and commercialization process, we will need to expand managerial, operational, financial and other resources in order to manage our operations, preclinical and clinical trials, research and development activities, regulatory filings, manufacturing and supply activities, and any marketing and commercialization activities or contract with other organizations to provide these capabilities for us. As operations expand, we expect that we will need to manage additional relationships with various collaboration partners, suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures. Such growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we either internally, together with our collaboration partners or through third party contractors, as applicable:

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

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

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

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the Securities and Exchange Commission, or SEC, which generally require our senior management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the year ended December 31, 2015, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to

no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our IPO, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, or (3) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which means the market value of the ADS and our ordinary shares that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (4) the date on which we have issued more than an aggregate of $1.0 billion in non-convertible debt during the prior three-year period.

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

We have identified material weaknesses in our internal control over financial reporting as of December 31, 2015. If we fail to remediate these weaknesses and maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us and could have a material adverse effect on the price of our ADSs.

In accordance with Section 404, management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015 and based on our management's assessment using criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework, management concluded that our internal control over financial reporting was not effective as of December 31, 2015. However, management identified two control deficiencies that constitute material weaknesses. Firstly, a material error in research and development costs for the year ended December 31, 2015 was identified and corrected. Due to a material weakness in the design of our controls related to the recognition of costs for deliverables under our supplier agreements, research and development costs were overstated by an amount that should have been recognized in the following financial year. Secondly, we commenced but did not complete the design and implementation of adequate internal controls relating to entity-level controls, controls over financial reporting and controls over our IT applications.

We have developed and begun implementing a remediation plan for these material weaknesses and despite our expectations regarding our remediation plan, our remediation plan may not be effective to fully remediate the internal control weaknesses. We cannot assure that you our remediation efforts will be successful or that similar material weaknesses will not recur, nor that we will able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. If we cannot in the future favorably assess the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on the trading price of our ADSs.

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;

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

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

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

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

- up-front, milestone and royalty payments, equity investments and financial support of new research and development candidates including increase of personnel, all of which may be substantial;
- exposure to unknown liabilities, including potential indemnification claims from a potential spin-off or out-license of certain of our intellectual property rights;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher-than-expected acquisition and integration costs;
- lower-than-expected benefits, from out-licensing or selling our technology, intellectual property or any of our subsidiaries or, from in-licensing intellectual property or purchasing assets;
- write-downs of assets or goodwill or impairment charges;
- difficulty and cost in combining or separating the operations and personnel of any acquired or sold businesses with our existing operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired or sold businesses due to changes in our senior management and ownership; and
- inability to retain key employees of any acquired businesses.

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

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

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

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

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

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

- different regulatory requirements for drug approvals in foreign countries;
- differing U.S. and non-U.S. drug import and export rules;
- reduced protection for intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems, and different competitive drugs;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from development work conducted by these distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

The manufacture of our TransCon product candidates is dependent upon third party manufacturers that are based in other parts of the world, including Europe, Japan and Australia. 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 is supplied by Hospira Adelaide Pty Ltd., and our drug substance and drug product for TransCon hGH are made by Rentschler Biotechnologie GmbH, or Rentschler, pursuant to our agreement with Rentschler. 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 EUROPE (Germany) GmbH supplies PEG and is responsible for coupling it to our TransCon linkers. We are currently qualifying Fujifilm Diosynth Biotechnologies UK Limited as a new supplier of our growth hormone parent drug and the 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 and, 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 delay 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 technology.

An important element of our strategy is to develop new products and product candidates based on our TransCon technology. 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 our Chief Scientific Officer, Dr. Harald Rau, and if we are not able to retain these members 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, and Dr. Harald Rau, our Chief Scientific Officer. The loss of services of either of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates.

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

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

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

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

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

Risks Related to Government Regulatory and Legal Requirements

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

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

Prior to obtaining approval to commercialize a drug candidate in the United States, the EEA or abroad, we or our collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the EMA, the FDA or other similar regulatory authorities, that such drug candidates are safe and effective for their intended uses. The number of nonclinical studies and clinical trials that will be required for FDA, or EMA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug 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 drug candidates are promising, such data may not be sufficient to support approval by the EMA, the FDA and other regulatory authorities. Administering drug 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 drug 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 products either prior to or post-approval, such as additional drug-drug interaction studies or safety or efficacy studies or trials, or it may object to elements of our clinical development program such as the number of subjects in our current clinical trials from the United States or Europe. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or result in a decision not to approve an application for regulatory approval. Despite the time and expense exerted, failure can occur at any stage. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

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

This lengthy approval process, as well as the unpredictability of the results of clinical studies, may result in our failure to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. Additionally, if the FDA requires that we conduct additional clinical studies, places limitations on our label, delays approval to market our product candidates or limits 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, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

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

We have not yet received any regulatory approvals required for the commercial sale of TransCon hGH, TransCon Treprostinil, or any of our other product candidates in the United States, the EEA or in any other jurisdiction. Furthermore, we have yet to submit an NDA to the FDA, or a Marketing Authorization Application, or MAA, to the EMA, national regulatory authorities in Europe or to any international regulatory authorities for any of our 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 our product candidates, or if we are required to generate additional data related to safety and efficacy, in order to obtain approval under Sections 505(b)(1) or 505(b)(2) of the FDA for any of our product candidates, we may be unable to meet our anticipated development and commercialization timelines.

In certain circumstances, such as with TransCon hGH, we plan to submit NDAs for our product candidates under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the Act. Section 505(b)(2) NDAs entail efforts to minimize data required in order to obtain marketing approval for a product candidate and therefore potentially a shortened development period for these applications. We cannot guarantee that any of our product candidates, including TransCon hGH, may be submitted under Section 505(b)(2) of the Act and the FDA has not confirmed to us that Section 505(b)(2) is an acceptable regulatory approval pathway for TransCon hGH or any of our other product candidates. In addition, our regulatory strategy of utilizing a single Phase 3 clinical study utilizing the active comparator Genotropin® in order to support an NDA submission for TransCon hGH for indications beyond pediatric GHD relies upon the Section 505(b)(2) approval pathway and, if this pathway is not accepted by the FDA, we would be required to pursue multiple pivotal clinical trials with TransCon hGH in order to obtain the necessary regulatory approvals to pursue these additional indications.

While we have an active IND with the FDA for TransCon hGH, we have not had substantive discussions with the FDA regarding the development of TransCon hGH in pediatric indications, or the nature or extent of studies we may be required to conduct in order to achieve approval of TransCon hGH in the United States for pediatric indications. The timeline for submission and review of our MAAs and NDAs is based on our plan to submit those materials, wherein we will rely in part on data in the public domain or prior conclusions of safety or effectiveness concerning a drug. We have not yet filed an MAA with the EMA for any of our product candidates. Depending on the data that may be required by the EMA for approval, some of the data may be related to products already approved by the EMA. If the data relied upon is related to products already approved by the EMA and covered by data we could be required to conduct substantial new research and development activities beyond those in which we currently plan to engage in order to obtain approval of our product candidates. Such additional new research and development activities would be costly and time consuming.

We are developing a pen device and higher-strength formulation of TransCon hGH to facilitate the administration of the product by end-users and additional time may be required to obtain regulatory approval for our pen device or higher-strength formulation.

We are developing a pen device with Medicom Innovation Partner A/S to facilitate the administration of TransCon hGH by patients. We anticipate the EMA, the FDA and other similar regulatory authorities will require a separate approval of our pen device that is in addition to the approval we are seeking for the drug component of TransCon hGH. Because of our pen device, the FDA's review of TransCon hGH 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. As a result, we may experience delays for our pen device and TransCon hGH.

We are currently conducting a Phase 1 comparability study of a higher-strength formulation of TransCon hGH that we believe would enable smaller injection volumes of TransCon hGH for patients with GHD as well as those who may require higher doses of TransCon hGH, such as those being treated with growth hormone for conditions such as Turner Syndrome or Idiopathic Short Stature. Failure to successfully develop this higher-strength formulation may require larger injection volumes for certain patients requiring higher doses of TransCon hGH than what is typically used to treat GHD patients.

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

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

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

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

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

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

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

all areas of regulatory compliance, including manufacturing, production, and quality control. Regulatory authorities may also impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs to assure compliance.

In the United States, advertising and promotional materials must comply with FDA rules in addition to other potentially applicable U.S. laws. In particular, the promotional claims that we would be permitted to make for our products would be limited to those supported by the approved product labeling. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the FDA's cGMP requirements. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. Sales, marketing, and scientific/educational grant programs must comply with the U.S. Anti-Kickback Statute, the False Claims Act, as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended. 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 drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have FDA approval.

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

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

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

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

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

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

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

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. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

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

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

We depend on third parties to manufacture products employing our technology. 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 technology. After regulatory approvals or licensure are obtained, the subsequent discovery of previously unknown manufacturing, quality control or regulatory documentation problems or failure to maintain compliance with the regulatory requirements may result in restrictions on the marketing of a product, revocation of the license, withdrawal of the product from the market, seizures, injunctions, or criminal sanctions. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaboration partners, or our contract manufacturers must supply all necessary documentation in support of an NDA, MAA or comparable regulatory filing on a timely basis and must adhere to cGMP regulations enforced by the FDA, EEA Competent Authorities and other regulatory authorities through their facilities inspection programs. Some of our contract manufacturers have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel.

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

If we, our collaboration partners, or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug 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, a supplemental NDA, a marketing authorization variation application or equivalent foreign regulatory filing, which could result in further delay. The regulatory authorities may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

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

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

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

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

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

Over the past several years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector

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

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

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

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

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

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (1) FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) U.S. federal and state fraud and abuse and other healthcare laws and regulations; or (4) laws that require the reporting of true and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These activities also include the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. 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, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

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

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

In the EEA, marketing authorization applications for new medicinal products not authorized 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 PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide

pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the European Union and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension. For orphan-designated medicinal products, the 10-year period of market exclusivity is extended to 12 years. At this time, we have not agreed to a PIP with the PDCO for TransCon hGH, or any of our other product candidates.

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

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

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

- the U.S. Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under U.S. federal healthcare programs such as the Medicare and Medicaid programs;
- U.S. false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- U.S. federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the U.S. Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal physician sunshine requirements under the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- state law equivalents of each of the above U.S. federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers;

- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;
- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, amends the intent requirement of the U.S. federal Anti-Kickback Statute and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

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

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 Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

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

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

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

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Tax Payer Relief Act was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals.

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 technology 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 technology, we file, prosecute and maintain international, U.S., European and other national patent applications covering such technology.

As of December 31, 2015, eleven patents have been issued to us in the United States. Nine of these patents are directed to our TransCon technology and one is directed to TransCon hGH. In addition, as of December 31, 2015, we have approximately 45 issued patents in jurisdictions outside of the United States, at least 30 of which are directed to our TransCon technology, and 14 of which are directed to our product candidates. We are not aware of any challenge to our issued patents, in the United States, Europe or in any other jurisdiction.

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

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

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

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;

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

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

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

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

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

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

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

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

Depending upon a complex analysis of a variety of legal and commercial factors, we and our collaboration partners may, in certain circumstances, including upon expiration of a potential 30-month automatic stay on the FDA's ability to grant final approval of a 505(b)(2) NDA, elect to market the relevant product candidate after FDA approval, even though litigation is still pending. This could occur before any court decision or while an appeal of a lower court decision is pending. Should we and our collaboration partners elect to proceed in this manner, we could face substantial patent liability damages, including possible triple damages in the United States, if a final court decision is adverse to us. If we and our collaboration partners are unsuccessful in any such litigation, the court could issue a permanent injunction preventing us from marketing our product candidates for the life of the litigated patent(s). In addition, such patent litigation could last for years, potentially delaying the commercialization of our product candidates until expiration of the relevant patents. Regulatory approval of pharmaceutical products in Europe is not linked to patent rights and patent disputes as it is in the United States. However, patent litigation is more cumbersome in Europe because enforcement is on a country-by-country basis and there are a number of countries where the relevant patents may be in force.

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

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

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

Litigation may be necessary to:

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

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

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

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or

Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first to file" system. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaboration partners' patent applications and the enforcement or defense of our or our collaboration partners' issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. 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, 2015, 44 of our employees work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees are generally subject to the provisions of the German Act on Employees' Inventions, which regulates the ownership of, and compensation for, inventions made by employees. Under this act, we face the risk that we may be required to pay additional compensation for assigned patent rights and disputes can occur between us and our employees or ex-employees pertaining to alleged non-adherence to the provisions of this act that may be costly to defend and consume our management's time and efforts whether we prevail or fail in such dispute. In addition, under the German Act on Employees' Inventions, certain employees may have retained rights to patents they invented or co-invented before October 2009. Although substantially all of these employees have assigned their interest in these patents to us, to the extent permitted by law, there is a risk that the compensation we provided to them may be deemed to be insufficient and we may be required under German law to increase the compensation due to such employees for the use of the patents. In those cases where employees have not assigned their interests to us, we may need to pay compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, our results of operations could be adversely affected.

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

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

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

We use various trademark rights in our business, including, Ascendis, and our trade name TransCon. Ascendis is our only registered trademark in the United States. We may not be able to obtain trademark protection in other territories that we consider of significant importance to us. Furthermore, we have not yet registered trademarks for a commercial trade name for any of our product candidates in the United States or elsewhere. During trademark registration proceedings, our trademark applications may be rejected. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in

comparable agencies in many foreign jurisdictions, third parties can oppose pending trademark applications and seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing our products under new brands.

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

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

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

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

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

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

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

Risks Related to Our Ordinary Shares and ADSs

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

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

- results from, or any delays in, clinical trial programs relating to our product candidates, including clinical trials for our lead product candidate, TransCon hGH;
- 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 future collaborations or our existing collaborations, including decisions regarding the exercise by our collaboration partners of their options, if any, or any termination by them of their collaborations with us;
- timing and amount of payments to us under our collaborations, if any;
- announcements of therapeutic innovations or new products by us or our competitors;
- announcements regarding the parent drugs that we use in developing our product candidates;
- adverse actions taken by regulatory authorities with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our product candidates;
- any adverse changes to our relationship with any manufacturers or suppliers;
- the success of our testing and clinical trials;
- the success of our efforts to acquire or 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;
- EMA, FDA or other similar regulatory actions affecting us or our industry or other healthcare reform measures in the United States;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of the ADSs;
- sales of our ordinary shares and/or ADSs by us, our senior management and board members, holders of the ADSs or our shareholders in the future;
- general economic and market conditions and overall fluctuations in the United States and international equity markets; and
- the loss of any of our key scientific or senior management personnel.

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

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

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

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

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

ADS holders may instruct the depositary of their ADSs to vote the ordinary shares underlying their ADSs. Otherwise, ADS holders are not able to exercise their right to vote, unless they withdraw the ordinary shares underlying the ADSs they hold. However, they may not know about the meeting far enough in advance to withdraw those ordinary shares. If we ask for instructions from ADS holders, the depositary, upon timely notice from us, will notify the ADS holders of the upcoming vote and arrange to deliver our voting materials to the ADS holders. We cannot guarantee that ADS holders will receive the voting materials in time to ensure that such holders can instruct the depositary to vote the ordinary shares underlying their ADSs or to withdraw the ordinary shares underlying their

ADSs so that they can vote such shares directly. If the depositary does not receive timely voting instructions from an ADS holder, the depositary may give a proxy to a person designated by us to vote the ordinary shares underlying ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that ADS holders may not be able to exercise any right to vote, and there may be nothing an ADS holder can do if the ordinary shares underlying their ADSs are not voted as they requested.

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

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

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

Our senior management has broad discretion over the use of proceeds from our initial public offering, and we could spend the proceeds from that offering in ways the holders of shares or ADSs may not agree with or that do not yield a favorable return, if at all. We currently intend to use substantially all of the net proceeds from that offering to fund our clinical development of TransCon hGH, to fund development of other TransCon product candidates, including TransCon Treprostinil, to strengthen our TransCon technology and for working capital and general corporate purposes. However, our use of these proceeds may differ substantially from our current plans. If we do not invest or apply these proceeds in ways that improve our operating results, we may fail to achieve expected financial results, which could cause the price of the ADSs to decline.

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

The trading market for the ADSs may be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, the price of our ADSs would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause the price of our ADSs or trading volume to decline.

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

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

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

If our existing shareholders or holders of ADSs sell, or indicate an intention to sell, substantial amounts of our ordinary shares or ADSs in the public market, the trading price of our ADSs could decline. Based upon the number of shares outstanding as of March 31, 2016, we have outstanding a total of 25,128,242 ordinary shares. Of those shares, approximately 11,217,884 were owned by current board members, members of our senior management and their respective affiliates, or may otherwise be subject to Rule 144 under the Securities Act. In addition, pursuant to a registration statement on Form F-3 filed in February 2016, 11,407,904 of our ordinary shares are registered for resale by certain selling shareholders, including shareholders that are affiliated with members of our board of directors.

As of March 31, 2016, there were 2,615,903 warrants outstanding. If these warrants are exercised an additional 2,615,903 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 31, 2016, our senior management, board members, holders of 5% or more of our share capital and their respective affiliates beneficially own approximately 80% of our outstanding voting securities. As a result, these security holders have the ability either alone or voting together as a group to determine and/or significantly influence the outcome of matters submitted to our shareholders for approval, including the election and removal of board members, payment of dividends, amendments to our articles of association, including changes to our share capital or any mergers, demergers, liquidations and similar transactions. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares or ADSs that our shareholders or ADS holders may feel are in their best interest as a shareholder or holder of ADSs. In addition, this group of shareholders may have the ability to control our management and affairs. Such control and concentration of ownership may affect the market price of the ADSs and may discourage certain types of transactions, including those involving actual or potential change of control of us (whether through merger, consolidation, take-over or other business combination), which might otherwise have a positive effect on the market price of the ADSs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We qualify as a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We may no longer be a foreign private issuer as of June 30, 2016, 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, 2017. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares or ADSs must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must not be administered principally inside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and NASDAQ rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

We may be a "passive foreign investment company" for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. investors.

Based on the current market price of the ADSs, and the value and composition of our income and assets, we do not believe we were a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for our taxable year ended December 31, 2015. However, the application of the PFIC rules is subject to uncertainty in several respects, and we cannot assure you that 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 (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. Because the value of our assets for purposes of this determination 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. A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). If we are a PFIC for any taxable year during which a U.S. Holder (as defined in "Item 10 E. Additional Information—Taxation—Material U.S. Federal Income Tax Consequences to U.S. Holders") holds ordinary shares or ADSs, the U.S. Holder may be subject to adverse tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of an interest charge with respect to such gain and certain dividends and (iii) compliance with certain reporting requirements. Each U.S. Holder is strongly urged to consult its tax advisor regarding these issues. See "Item 10 E. Additional Information—Taxation—Material U.S. Federal Income Tax Consequences to U.S. Holders."

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, in order 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 equityholding in the event of future issuances of our shares.

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

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

Item 4 *Information on the Company*

A. History and Development of the Company

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

Our registered office and principal executive offices are located at Tuborg Boulevard 5, DK-2900 Hellerup, Denmark and our telephone number is +45 36 94 44 86. Our agent for service of process in the United States is Ascendis Pharma, Inc. Our website address is www.ascendispharma.com. The information on, or that can be accessed through, our website is not part of and should not be incorporated by reference into this 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.

For additional information relating to the development of our company, see "Item 4 B. Information on the Company – Business Overview."

B. Business Overview

Overview

We are a clinical stage biopharmaceutical company applying our TransCon technology to develop a pipeline of long-acting prodrug therapies with best-in-class profiles to address large markets with significant unmet medical needs. We are developing our lead product candidate, TransCon human growth hormone, or TransCon hGH, for once-weekly administration to treat growth hormone deficiency, or GHD, and other indications. We have successfully completed Phase 2 studies of TransCon hGH in children and adults with GHD. In July 2015, we announced positive top-line results from a six-month Phase 2 study to evaluate the safety and efficacy of once-weekly TransCon hGH in 53 treatment-naïve, pre-pubertal children with GHD. Using our TransCon technology, we have established a new paradigm that combines the benefits of conventional prodrug and sustained release technologies, and is broadly applicable to proteins, peptides and small molecules. In addition to TransCon hGH, we have developed a pipeline of long-acting prodrug product candidates such as TransCon Treprostinil for the treatment of pulmonary arterial hypertension, or PAH, TransCon Peptides, for the treatment of diabetes, partnered with Sanofi, and TransCon Ranibizumab, in the field of ophthalmology, partnered with Genentech.

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 premature mortality, increased adiposity, or fat mass, as well as psychiatric-cognitive, cardiovascular, muscular, metabolic and skeletal abnormalities. Human growth hormone, or hGH, is used for the long-term treatment of children and adults that fail to secrete adequate amounts of endogenous growth hormone. According to Medtrack, global sales from currently marketed hGH products grew to over $3 billion in 2014.

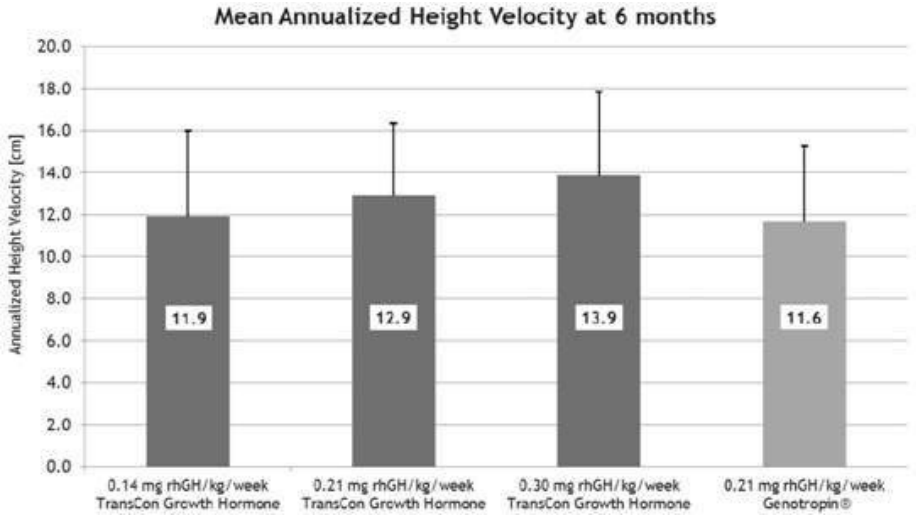
The use of recombinant hGH was introduced in 1981, and since then many of the world's largest pharmaceutical companies have developed and now market daily hGH injections as the current standard of care for the treatment of GHD. Despite the demonstrated benefits of hGH therapy, published studies have shown that the majority of patients on a daily hGH regimen are not fully compliant with their daily dosing schedule, which in pediatric patients has led to significant reductions in treatment outcomes. 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. To date, regulatory authorities have approved only two long-acting growth hormone products, each of which utilize unmodified growth hormone as the active drug substance. Neither of these products has achieved commercial success, due to manufacturing, regulatory, efficacy safety and/or tolerability reasons associated with the sustained release technology. To address the unmet medical needs of GHD, we are developing TransCon hGH for once-weekly administration. TransCon hGH is a prodrug that releases unmodified growth hormone and thus maintains the same mode of action as currently prescribed daily hGH therapies, which we believe reduces clinical and regulatory risk. If approved, TransCon hGH may reduce the burden of daily treatment by requiring significantly fewer injections, which may improve compliance and treatment outcomes.

In order to achieve regulatory and commercial success, we believe that a new long-acting hGH product must provide a comparable safety, efficacy and tolerability profile to currently marketed daily hGH therapies. We have been developing TransCon hGH to provide patients, physicians, regulators, third-party payors and managed care administrators with a product profile that builds upon the longstanding and trusted use of currently approved daily hGH therapies, but in a dosage form that allows for once-weekly as opposed to daily injections. Key parameters of this profile include:

- Height velocity: First-year height velocity comparable to daily hGH
- Mode of action: TransCon prodrug liberates unmodified hGH
- Safety: IGF-I and hGH levels comparable to those achieved with daily hGH therapies
  No nodule formation
  No lipoatrophy
  Immunogenic profile comparable to daily hGH therapy
- Tolerability: <1.0 mL per injection
  30 gauge, or finer, needle
- Device: Convenient and easy-to-use

On July 30, 2015, we announced positive top-line results from a six-month Phase 2 study to evaluate the safety and efficacy of once-weekly TransCon hGH in 53 treatment-naïve, pre-pubertal children with GHD.

The Phase 2 pediatric study was conducted to investigate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of TransCon hGH in treatment-naïve pre-pubertal children with GHD who meet internationally recognized diagnostic criteria for GHD. The study enrolled 53 patients into the treatment phase and was a 6-month multi-center, randomized, open-label study comparing three dose levels of TransCon hGH (0.14; 0.21; and 0.30 mg hGH/kg/week), administered once per week, to the active control Genotropin (0.21 mg hGH/kg/week), administered as a daily injection.



Highlights from the top-line analysis include:

- mean annualized height velocities among the three dosing levels administered weekly ranged from 11.9 cm for the 0.14 mg/kg/week dose to 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;
- there were no reports of drug-related serious or unexpected adverse events;
- injection site reactions were generally mild and transient and were observed at a rate that was similar to the daily hGH control arm;

- there were no observations of injection site nodule formation or lipoatrophy;
- low immunogenicity consistent with published data for daily growth hormone, with no neutralizing antibodies;
- maximum hGH blood concentration was comparable between equivalent weekly doses of TransCon hGH and daily hGH; and
- a dose-proportional increase in IGF-I levels was observed following dosing of the three TransCon hGH dose levels. Consistent with expectations, transient point values of IGF-I standard deviation score > +2 have been observed in a small number of patients and primarily in the high-dose treatment arm.

The data announced represent a top-line analysis. We released the full data set for the Phase 2 pediatric study in October 2015 at the annual meeting of the European Society for Pediatric Endocrinology, and intend to initiate a Phase 3 pediatric study of TransCon hGH in mid-2016. As currently planned, this pivotal study will be a 12-month, parallel-group study evaluating a single dose of TransCon hGH versus daily injections of growth hormone, and will be primarily conducted in centers across Europe and North America. We believe a single Phase 3 study will support regulatory approval of TransCon hGH in Europe and the U.S. We are also developing a pen device with Medicom Innovation Partner A/S for administration of TransCon hGH that is designed to be easy-to-use in the pediatric population and leverages proven technologies.

We are also developing TransCon Treprostinil for the treatment of PAH, a life-threatening disease characterized by elevated blood pressure in the pulmonary arteries. According to Medtrack, the worldwide market for PAH treatment exceeded $4 billion in 2014. Treprostinil, the active agent in Remodulin®, marketed by United Therapeutics, belongs to a class of drugs known as prostacyclins, and is the leading infused therapy for the treatment of PAH. TransCon Treprostinil is designed as a once-daily self-administered subcutaneous injection, offering the same efficacy as continuously infused prostacyclins with a safer and improved tolerability profile. TransCon Treprostinil is expected to offer significant advantages as compared to currently infused prostacyclin therapies, including minimizing injection site pain and the risk of bloodstream infection. In April 2015 we announced data from the Phase 1 single ascending dose study of TransCon Treprostinil. TransCon Treprostinil produced dose-dependent increases in plasma Treprostinil levels in line with expectations. However, Treprostinil-related injection-site tolerability issues did not meet the criteria defined in the target product profile. We are conducting additional research on new product formulations of TransCon Treprostinil and plans to resume clinical development when product improvements to mitigate current limitations have been addressed.

In addition to our proprietary programs, we have formed multi-product collaborations with leading biopharmaceutical companies on market-leading products and in therapeutic categories of strategic importance to our collaboration partners. These collaborations are with Sanofi in the field of diabetes and with Genentech in the field of ophthalmology. Additionally, we are eligible to receive up to an aggregate of €200 million in development and regulatory milestone payments for products currently being developed under our collaboration agreements, as well as sales-based milestone payments and royalties on future net sales of products.

Our TransCon technology enables us to create long-acting prodrug therapies with potentially significant advantages over existing marketed drug products. Conventional prodrugs are inactive, or significantly less active, forms of a parent drug that are designed to be activated only after undergoing transformation in the body, for example when enzymes cleave the parent drug from a prodrug molecule. Our TransCon technology transiently links an unmodified parent drug to a TransCon carrier via our proprietary TransCon linkers. Our TransCon linkers predictably release an unmodified active parent drug at predetermined rates governed by physiological pH and temperature conditions, supporting administration frequencies from daily up to half-yearly. TransCon prodrugs may offer safety, efficacy and tolerability advantages over the original parent drug and as compared to other technologies used to extend drug residence time in the body. Depending upon the type of TransCon carrier we employ, we can design our TransCon prodrugs to act systemically or locally in areas that are difficult to treat with conventional therapies.

TransCon Product Candidate Pipeline

The table below depicts the current development status of our product candidates:

Product Candidate	Primary Indication	Approved Parent Drug	Stage of Development	Market Size	Worldwide Commercial Rights
TransCon Growth Hormone	Pediatric Growth hormone deficiency	✓	Phase 3 (initiation planned mid-2016)	> $3 billion	ascendis pharma
	Adult Growth hormone deficiency	✓	Phase 2		ascendis pharma
TransCon Treprostinil	Pulmonary Arterial Hypertension	✓	Phase 1	> $1 billion	ascendis pharma
TransCon Ranibizumab	Ophthalmology	✓	Preclinical	> $7 billion	Genentech A Member of the Roche Group
TransCon Peptides	Diabetes		Preclinical	> $1 billion	SANOFI

When we apply our TransCon technology to already approved drug compounds, we may benefit from established clinical safety and efficacy data, which we believe reduces drug development risk and may allow us to utilize expedited approval pathways provided by the FDA and European regulatory authorities. Examples of regulatory strategies that may be available to us or our collaboration partners include the FDA's section 505(b)(2) regulatory approval pathway, which was established to allow companies developing drug products to obtain approval by relying in part on studies of safety and effectiveness that were not conducted by or for the applicant. Because approval can rest in part on data already accepted by the FDA or otherwise available in the public domain, fewer and smaller studies may be required, thus mitigating costs and shortening development time. Section 505(b)(2) filings can provide expedited approval for a wide range of products, especially for those that represent a limited change from an existing or approved drug, including prodrugs of already approved parent drugs. We plan to pursue a 505(b)(2) regulatory strategy for TransCon hGH. If successful in this strategy, it is possible that a single Phase 3 clinical study utilizing the active comparator Genotropin®, could support our NDA submission to the FDA for its review of TransCon hGH for pediatric GHD and other indications.

We maintain an intellectual property portfolio comprising approximately 57 issued patents and more than 200 patent applications as of December 31, 2015, with claims directed to composition of matter, process, formulation and/or methods-of-use for our product candidates and core TransCon technology. In addition, each of our collaboration partners has granted us rights that enable us to freely commercialize all improvements to the TransCon technology developed by our collaboration partners outside of the field identified in their respective collaboration agreements. We hold worldwide rights to our TransCon technology and have no third-party royalty or milestone payment obligations with respect to our TransCon technology 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 leverage our TransCon technology to create a pipeline of proprietary products and form collaborations with market-leading biopharmaceutical companies to develop new products that incorporate our TransCon technology in therapeutic areas that are of strategic importance.

Key elements of our strategy to achieve this goal include:

- *Leverage our TransCon technology to create a pipeline of new product candidates with best-in-class therapeutic profiles in large markets:* Our goal is to create a robust pipeline of innovative, best-in-class therapeutics that capitalize upon the unique advantages of our TransCon technology. We intend to develop new TransCon-based product candidates in multi-billion dollar markets where we believe we can meaningfully improve the existing standard of care. We believe the data from our Phase 2 pediatric study of TransCon hGH supports our ability to develop a best-in-class therapeutic for treatment of GHD.
- *Complete the clinical development of TransCon hGH to support regulatory approval for the treatment of GHD and other indications:* We have successfully completed Phase 2 studies of TransCon hGH in children and adults with GHD. In July 2015, we announced positive top-line results from a six-month Phase 2 study to evaluate the safety and efficacy of once-weekly TransCon hGH in 53 treatment-naïve, pre-pubertal children with GHD. We expect to conduct an End of Phase 2 meeting with the FDA and consult with the EMA. Depending on feedback we may receive from the FDA and the EMA, we intend to initiate a Phase 3 pivotal trial of TransCon hGH in mid-2016.
- *Continue to establish strategic collaborations with market-leading biopharmaceutical companies:* We intend to enter into additional collaborations with market-leading biopharmaceutical companies to develop and commercialize products in therapeutic categories of strategic importance to our collaborators. We will seek opportunities to structure our collaborations in ways that allow us to retain development and commercialization rights in key specialty markets where we can maintain a focused sales force. We expect our collaborations to provide substantial up-front technology licensing fees, development milestone payments and/or royalties, and reimburse us for the time we spend assisting them with research and development activities. This reduces our dependence on the financial markets to fund on-going operations and our development programs.
- *Pursue expedited regulatory pathways:* We intend to pursue the fastest feasible pathways to approval for our portfolio of product candidates. Because our TransCon technology enables the sustained release of an unmodified parent drug with established clinical safety, efficacy and tolerability, we believe, in many cases, that we will be in a position to pursue an expedited clinical development and regulatory approval pathway as compared to the development of traditional new molecular entities. These may include the Section 505(b)(2) approval pathway in the United States and similar pathways in non-U.S. markets, which pathway allows us to rely in part on studies of safety and effectiveness that were not conducted by us or on our behalf.
- *Strengthen our leadership position in the field of long-acting prodrug technology:* We believe that our deep experience base in developing TransCon-based product candidates establishes us as the leader in long-acting prodrug technology, and we intend to further strengthen this leadership position through investment in our TransCon technology, new technologies, our lab, clinical and commercial scale manufacturing capabilities and our methods and know-how. In partnership with our collaborators, we have developed a powerful and integrated set of capabilities that are critical to our ability to rapidly and efficiently develop, optimize and scale-up manufacturing for new TransCon-based product candidates. In addition, each of our collaboration partners has granted us rights that enable us to freely commercialize all improvements to the TransCon technology developed by our collaboration partners outside of the field identified in their respective collaboration agreements.

TransCon Technology

Overview: Prodrugs and Technologies to Extend Drug Exposure

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 applied to improve drug characteristics, such as prodrug and sustained release technologies.

A prodrug is an inactive or significantly less active form of a parent drug, and prodrug technology has been used to improve drug characteristics such as absorption, distribution, metabolism and excretion. Prodrugs require transformation into the active drug after administration to the patient. Conventional prodrug technologies rely upon metabolic processes, such as enzymatic conversion or spontaneous hydrolysis, to release the active drug. These technologies do not facilitate predictable release of the parent drug or provide for an extended duration of action. Metabolic conversion of prodrugs may differ between patients, and even within different tissues within the same patient, and spontaneous hydrolysis is generally a rapidly occurring process which may result in a release of high concentrations of the active drug.

Several technologies have been developed to extend drug exposure, including technologies that permanently modify the drug molecule. Protein enlargement technologies, such as permanent PEGylation and protein fusion, work by enlarging the size of a drug molecule, which reduces the body's ability to excrete the analog and thereby extends duration of action. As the analog resulting from these technologies is no longer identical to the parent drug, it may have a different mode of action within the body that can lead to altered safety and efficacy outcomes. Generally, the half-life extension achievable with protein enlargement technologies extends up to two weeks.

Similarly, modification of drug molecules with fatty acids can facilitate binding to albumin, a naturally occurring protein, which delays excretion of the drug-fatty acid derivative and imparts an extended half-life as compared to the unmodified drug. This approach has been applied to create approved drugs with daily administration profiles. Published data from development stage compounds suggest that once-weekly dosing profiles for peptides can be achieved, but less sustained half-life extension is achieved when applied to proteins.

Encapsulation is a different approach to extending drug exposure without altering or modifying the structure of the parent drug, thus maintaining the parent drug's original mode of action. The parent drug is encapsulated in an inactive polymer matrix, which releases the unmodified drug both by diffusion through the polymer matrix and by biodegradation of the polymer itself. Drug release from encapsulated drug depots generally occurs in multiple phases and is characterized by a rapid burst release followed by a period of slower drug release. The initial high drug levels from the burst release may be associated with a higher risk of side effects. In addition, the polymers used for encapsulation are frequently associated with adverse reactions at the injection site, which may negatively affect tolerability. Furthermore, encapsulation approaches are known to activate the immune system, causing an antibody response to proteins and peptides formulated with these technologies.

Our TransCon Technology

Our TransCon technology is 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. Our TransCon technology establishes a new paradigm that combines the benefits of conventional prodrug and sustained release technologies, and is broadly applicable to proteins, peptides and small molecules. TransCon prodrugs predictably release unmodified active parent drugs and may offer advantages that include superior efficacy, safety, tolerability and compliance, including less frequent dosing and the ability to switch patients to subcutaneous injections from burdensome continuous infusions and less frequent dosing.

Our TransCon technology is differentiated in that it enables us to design long-acting prodrugs that predictably release an unmodified active parent drug. Our TransCon linkers predictably release an unmodified active parent drug at predetermined rates governed by physiological pH and temperature conditions, supporting administration frequencies from daily up to half-yearly. TransCon prodrugs may offer safety, efficacy and tolerability advantages over the original parent drug and as compared to other technologies used to extend drug residence time in the body. 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.

Advantages of our TransCon technology

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

Efficacy

- Predictable release of unmodified parent drug supporting daily to half-yearly administration
- Enables localized or systemic drug exposure
- Reduces dosing frequency to improve patient compliance and improve overall treatment outcome

Safety and Tolerability

- Same mode of action as parent drug
- Minimizes injection site reactions
- Enables switch from continuous infusions to daily or less frequent subcutaneous injections
- Immunogenic potential, or the ability of a substance to provoke an immune response, comparable to parent drug

Development and Regulatory

- Higher development success rate when incorporating approved parent drug
- May qualify for 505(b)(2) or similar non-U.S. approval pathways

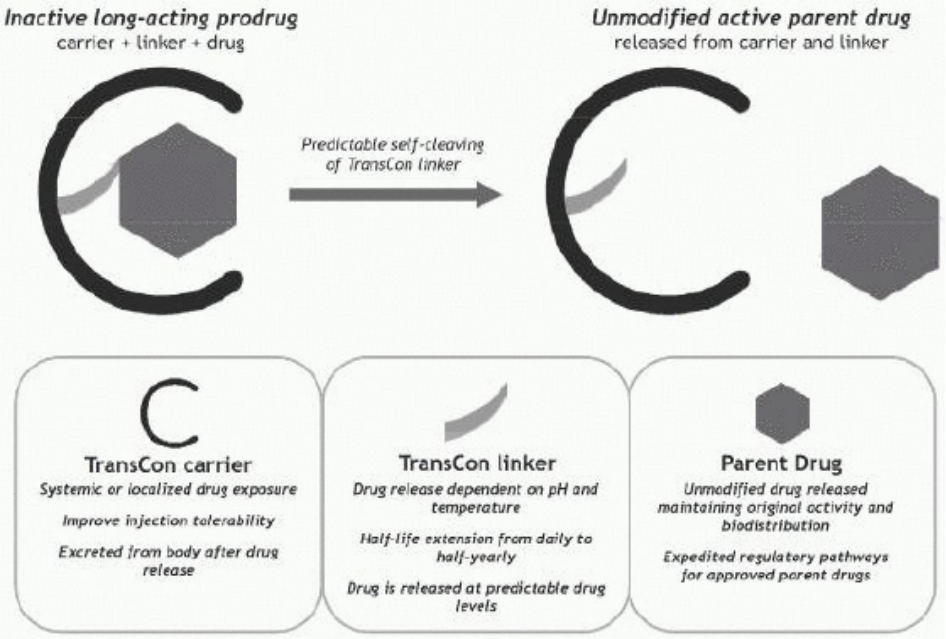
Intellectual Property

- New composition of matter patents

Technology Overview

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

Our TransCon carriers can be selected from our soluble or hydrogel carrier platforms. These carriers inactivate and protect the parent drug through a shielding effect, which prevents rapid excretion and degradation of the parent drug. The parent drug is connected to the carrier via the TransCon linker, which is designed to release the drug at a predictable and predetermined rate, enabling release of unmodified active parent drug with up to half-yearly administration. The TransCon linker is designed to remain attached to the TransCon carrier after release of the parent drug. Our broad selection of TransCon linkers, in combination with our soluble carriers and microparticle carriers, provides us with a powerful and flexible technology that we leverage to design best-in-class therapeutics aimed at multi-billion dollar markets. The broad applicability of the TransCon technology is reflected by the fact that our pipeline contains long-acting prodrugs incorporating proteins, peptides and small molecules.



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

TransCon Carriers

Our TransCon technology incorporates two carrier platforms that can be used for providing localized or systemic drug exposure. These biocompatible carrier platforms include our TransCon soluble carriers and our proprietary TransCon hydrogel carrier, which is a self-eliminating hydrogel. 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 soluble 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 soluble carriers are readily absorbed into the bloodstream after administration, thus minimizing exposure of the subcutaneous tissue to active drug, which we believe may improve injection site tolerability. Our most advanced product candidates, TransCon hGH and TransCon Treprostinil, utilize PEG as a carrier molecule. PEG is widely used to alter the pharmacokinetic or pharmacodynamic properties of marketed therapeutics.

- Our TransCon hydrogel carriers are being developed to provide either localized or systemic drug exposure. Our proprietary TransCon hydrogel is designed to be biocompatible and self-eliminating, and consists of microparticles that allow for highly efficient drug loading into the hydrogel via our TransCon linkers. The TransCon hydrogel is pre-formed and subsequently loaded with the parent drug, which can prevent adverse modification of the drug during manufacturing of the hydrogel. This process is proprietary, and we believe our granted patents prevent our competitors from creating prodrugs based on preformed hydrogels. Our current TransCon hydrogels are PEG-based and we are developing hydrogels based on hyaluronic acid and other biopolymers. Our TransCon hydrogel is designed to self-eliminate to soluble, biocompatible molecules after the drug payload has been released. We and our collaboration partners are developing the TransCon hydrogel in both systemic and localized drug delivery applications.

Parent drug

Our TransCon technology is applicable across a broad range of therapeutic classes, and is currently used to create superior long-acting product candidates based on proteins, peptides and small molecules. By primarily focusing on biological targets that have been clinically validated, we can leverage available knowledge regarding a target's activity. Based on this selective approach, we know what drug levels must be maintained in the body for optimal efficacy and safety, and we can design the release half-life 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 technology releases an unmodified drug with established clinical safety and efficacy, we believe we may benefit from a higher development and regulatory success rate as compared to development of drug compounds without established clinical data.

TransCon Product Candidates

TransCon human Growth Hormone (hGH)

Our lead product candidate is TransCon human Growth Hormone, or TransCon hGH, for the treatment of growth hormone deficiency, or GHD. Leading products for the treatment of GHD require that patients, the majority of whom are children, receive daily injections over many years. The burden of daily administration often results in poor patient compliance, potentially leading to suboptimal treatment outcomes. Despite this, global annual sales from currently marketed hGH products exceeded $3 billion in 2014 according to Medtrack. We are developing TransCon hGH as a prodrug with once-weekly administration that releases unmodified growth hormone, maintaining the same mode of action as daily hGH therapies. Clinical studies of TransCon hGH have demonstrated a comparable efficacy, safety, tolerability and immunogenic profile to that of daily growth hormone. If approved, TransCon hGH may reduce the burden of daily treatment by requiring significantly fewer injections, which may improve compliance and treatment outcomes. We have successfully completed Phase 2 studies of TransCon hGH in children and adults with GHD. In July 2015, we announced positive top-line results from a six-month Phase 2 study to evaluate the safety and efficacy of once-weekly TransCon hGH in 53 treatment-naïve pre-pubertal children with GHD. We plan to conduct an End of Phase 2 meeting with the FDA and consult with the EMA, and then initiate a Phase 3 study in growth hormone deficient children in mid-2016. In addition, we are developing a pen device with Medicom Innovation Partner A/S for administration of TransCon hGH that is designed to be easy-to-use in the pediatric population and leverages proven technologies.

Overview of Growth Hormone Deficiency

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 premature mortality, increased adiposity, or fat mass, as well as psychiatric-cognitive, cardiovascular, muscular, metabolic and skeletal abnormalities. Due to its small size, hGH distributes throughout the body, where it acts directly on organs and tissue. Through interaction with the GH receptors, which are present in virtually every tissue, hGH stimulates the production of IGF-I, or insulin-like growth factor I. IGF-I amplifies the anabolic effects of hGH, but has insulin-like effects in fat tissue, thus stimulating fat formation. This is in contrast to hGH which stimulates the breakdown of fat. hGH is used for the long-term treatment of children and adults that fail to secrete adequate amounts of endogenous growth hormone. Daily hGH therapies have been shown to increase growth and improve metabolic effects, including reducing adiposity and improving cardiovascular health. These therapies have been shown to be safe, well-tolerated and essentially pain-free upon injection. Compliant GHD children initially achieve "catch-up growth," enabling patients to approach or achieve normal height on a standard growth curve. Height velocity following the "catch-up" period normalizes, permitting the patients to maintain normal growth throughout the course of treatment. Patients that are non-compliant generally achieve lower "catch-up growth" and fail to achieve expected treatment outcomes. Primary indications for hGH in children are GHD, Idiopathic Short Stature, kidney disease, Prader-Willi Syndrome and Turner's syndrome. In adults, primary indications for hGH include GHD and AIDS-induced weight loss.

The use of hGH was introduced in 1981, and since then many of the world's largest pharmaceutical companies have developed and now market daily growth hormone injections. 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. To date, regulatory authorities have approved only two long-acting growth hormone products, each of which utilize unmodified growth hormone as the active drug substance. Neither of these products has achieved commercial success, due to manufacturing, regulatory, efficacy, safety and/or tolerability reasons.

After more than thirty years of collective industry experience with growth hormone development and commercialization, we believe that a clear set of product attributes has emerged as being necessary for clinical, regulatory and commercial success. We are developing TransCon hGH as a once-weekly therapy with a target profile designed to match that of daily growth hormone therapies on key parameters, including:

- Height velocity: First-year height velocity comparable to daily hGH
- Mode of action: TransCon prodrug liberates unmodified hGH
- Safety: IGF-I and hGH levels comparable to those achieved with daily hGH therapies
No nodule formation No lipoatrophy
Immunogenic profile comparable to daily hGH therapy
- Tolerability: <1.0 mL per injection
30 gauge, or finer, needle
- Device: Convenient and easy-to-use

Market Opportunity

According to Medtrack, global annual sales from currently marketed daily hGH injections exceeded $3 billion in 2014. We believe a significant market opportunity exists for a long-acting version of hGH with comparable efficacy, safety and tolerability as daily growth hormone products.

The current standard of care for GHD is daily subcutaneous injections of hGH. All currently marketed hGH products in the United States, Norditropin® (Novo Nordisk A/S), Humatrope® (Eli Lilly and Company), Nutropin AQ® (Genentech), Genotropin® (Pfizer Inc.), Saizen® (Merck Serono S.A.), Zomacton® (Ferring Pharmaceuticals, Inc.) and Omnitrope® (Sandoz GmbH), contain unmodified hGH and are administered by daily subcutaneous injections. The global market for daily hGH products is dominated by Novo Nordisk, Pfizer, Eli Lilly, Sandoz, Merck KGaA and Roche, which together account for approximately 95% of global market share.

Pediatric indications comprise up to 90% of the total hGH market, of which approximately half is for GHD. Patients treated with daily hGH typically receive thousands of injections over the course of many years. Growth hormone deficient children who are fully compliant with their daily treatment regimen may achieve a height in adulthood that is comparable to that of their family members and national norms. In therapy-compliant adults with GHD, daily subcutaneous injections of hGH have resulted in improved body composition parameters, bone density, cardiovascular outcomes and quality of life.

Despite the demonstrated benefits of hGH therapy, published studies have shown that the majority of patients on a daily hGH regimen are not fully compliant with their daily dosing schedule, and therefore fail to achieve expected treatment outcomes. For example, in a study published in PLOS One, in 2011, 66% of the patients missed more than one injection on average per week, leading to significant reductions in the degree of growth in pediatric patients. Reducing injection frequency is associated with better compliance and may improve height velocity for patients experiencing poor compliance with daily injections.

As shown in the figure below, for patients missing two or more injections per week there was a clinically relevant reduction in their change in height velocity standard deviation score, or HVSDS, compared to high-compliance patients. A greater HVSDS indicates more rapid growth:

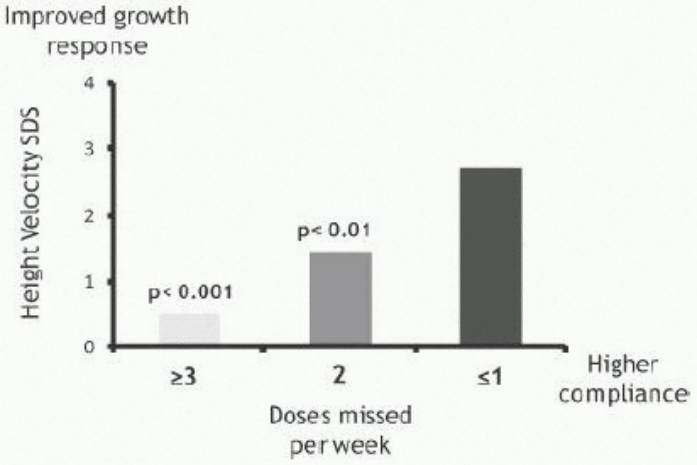


Figure 1. Negative impact of poor compliance on growth response. Patients missing two or more injections per week have a statistically significant reduction in height velocity. A result is considered statistically significant when the p-value, representing the probability that random chance could explain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

Limitations of Technologies Being Employed to Develop Long-acting hGH and hGH Analogs

Other companies are working on long-acting hGH or hGH analogs using technologies that generally fall into two categories: encapsulation and permanent hGH modification.

Encapsulation technologies

Encapsulation technologies have been applied to the only two long-acting hGH products to receive regulatory approval, Nutropin Depot®, formerly marketed by Genentech and Somatropin Biopartners developed by LG Life Sciences and Biopartners GmbH. In these formulations, unmodified growth hormone is released both by diffusion through the encapsulation polymer surrounding the growth hormone, and by biodegradation of the polymer. These products are associated with nodule formation, erythema, or redness of skin, itching, bruising, as well as pain during and after injection. In addition, high levels of antidrug antibodies have been observed following administration of these drugs to patients. We believe that the lack of market acceptance is a result of the various safety and tolerability issues that tend to arise with encapsulation technologies.

Modified growth hormone analogs

Modification technologies prolong growth hormone activity in the body by creating analogs of growth hormone through permanent modification of the growth hormone molecule. This modification may alter the molecular size and interaction with the growth hormone receptor and/ or change the natural association affinity to endogenous proteins, thereby reducing the body's ability to excrete the analog. We believe that these changes may alter the mode of action and distribution of modified growth hormone analogs into key growth hormone responsive tissues, such as brain, bone, muscle and fat, compared to unmodified growth hormone. These changes may alter and reduce the efficacy of these drugs compared to unmodified daily growth hormone and may also negatively impact the drug's safety. For instance, a modified growth hormone previously being developed by Pfizer was discontinued due to lipoatrophy, a condition of localized loss of fat tissue that can cause undesirable skin deformations, at the injection site following repeated administration in adult patients with GHD.

Previous attempts to develop a long-acting hGH by utilizing permanent modification of growth hormone have failed due to regulatory, safety, efficacy and manufacturing hurdles.

There are currently no long-acting growth hormone treatment options available in the United States or Europe. GeneScience Pharmaceuticals Co., Ltd., Genexine Inc., Hanmi Pharmaceutical, Novo Nordisk A/S, OPKO Health, Inc., Teva Pharmaceutical Industries Ltd. and Versartis, Inc. are developing long-acting growth hormone analogs based on permanent modification of growth hormone. In particular, we are aware that certain of these competitors have reported 6-month annualized height velocities ranging from 8.7 cm for a bi-weekly dosing frequency to 12.2-13.6 cm for a weekly dosing frequency.

Based on publicly available data for these product candidates, we believe that TransCon hGH may have comparative benefits. In particular, each of these permanently modified growth hormone product candidates are administered as a bolus injection, and our analysis of public data indicates that the initial blood concentration of growth hormone for these products exceeds levels typically observed following administration of daily growth hormone. We believe that TransCon hGH may have a more favorable safety profile because it results in growth hormone levels comparable to daily growth hormone. We also believe that it may not be possible to administer drug in less than 1 mL per injection for all GHD children with a dosing frequency of once every two weeks.

In addition to the currently approved and marketed daily growth hormone therapies, there are a variety of experimental growth hormone therapies in different stages of clinical development by various companies, including Bioton S.A., Critical Pharmaceuticals, Ltd., Dong-A Pharmaceutical, and all of the global and regional pharmaceutical companies with existing growth hormone franchises.

Our Solution: TransCon hGH

TransCon hGH is a novel long-acting prodrug of hGH that maintains the same mode of action as daily hGH therapies. In addition, clinical studies of TransCon hGH have demonstrated an efficacy, safety, tolerability and immunogenic profile that is comparable to that of daily growth hormone. TransCon hGH addresses the highest priority unmet medical need in growth hormone therapy by reducing the number of injections patients require, while leveraging the safety and efficacy data base that has been established with unmodified daily hGH products.

TransCon hGH is essentially inactive when administered. This improves injection site tolerability compared to other long-acting growth hormone products. Full activity of the parent growth hormone is restored when unmodified growth hormone is released from the prodrug. As long as the growth hormone is in the prodrug form, elimination from the body is minimized, ensuring a long half-life. The TransCon linker releases the

unmodified growth hormone in a self-cleaving process that relies on physiological pH and temperature conditions, ensuring the predictable release of growth hormone and enabling a once-weekly dosing regimen. We have conducted biopotency assays and generated mass spectrometry profiles demonstrating that the bioactivity and structure of growth hormone released from TransCon hGH is comparable to the growth hormone in marketed growth hormone products administered as daily injections. As such, we expect our once-weekly TransCon hGH to have the same mode of action and distribution into key growth hormone-responsive tissues, such as brain, bone, muscle, liver and fat tissue, as the hGH administered from daily injections and endogenous growth hormone. We use daily growth hormone as an active comparator in our clinical studies, allowing us to directly compare the activity of TransCon hGH to daily growth hormone in an identical clinical setting.

The primary measure of efficacy in our completed clinical studies was the temporal profiling of circulating plasma concentrations of insulin-like growth factor-I, or IGF-I. IGF-I is a well-established pharmacodynamic surrogate endpoint of hGH activity, and we have demonstrated that once-weekly administration of TransCon hGH results in IGF-I levels that are comparable to daily hGH when administered at an equivalent dose.

Clinical Development of Once-weekly TransCon hGH

Phase 1 ascending single-dose study in healthy adult volunteers

We initiated clinical development of once-weekly TransCon hGH in November 2009. In June 2010, we reported the successful completion of a single-center, double-blind, randomized, placebo and active controlled dose-ascending Phase 1 study of once-weekly TransCon hGH in 44 healthy adult volunteers in Canada. The study demonstrated a comparable IGF-I response, the primary biomarker of growth hormone efficacy, following a single administration of TransCon hGH versus seven daily injections of hGH, at comparable dose levels. We believe that the Phase 1 data also demonstrated that TransCon hGH was well-tolerated with a safety profile, including immunogenic potential and injection site reactions, that was comparable to that of daily injections of hGH over the course of the study.

Phase 1 single-dose study in healthy adult volunteers

In June 2012, we conducted a Phase 1 single-dose study of TransCon hGH for once-weekly administration. This trial continued for one week following the initial injection and included 24 healthy adult male and female volunteers, with testing dose levels up to 0.36 mg hGH/kg/week. We believe the safety profile observed in this Phase 1 study provides the foundation for studies in children with GHD, as this hGH dose is higher than the pediatric GHD doses generally used in Europe (0.21 mg hGH/kg/week) and in the United States (0.30 mg hGH/kg/week).

Higher-Strength Formulation: Phase 1 single-dose study in healthy volunteers

We are currently conducting a Phase 1 comparability study of a higher-strength formulation of TransCon hGH. In this study, we are comparing the pharmacokinetic and pharmacodynamics response between a single-dose of the higher-strength and the present formulation of TransCon hGH at comparable dose levels. We believe the higher-strength formulation of TransCon hGH would allow smaller injection volumes of TransCon hGH for both patients with GHD as well as for high-dose growth hormone indications, such as patients with Turner Syndrome and Idiopathic Short Stature.

Phase 2 multi-dose study in adult patients

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

In this study, serum levels of free hGH and TransCon hGH increased proportionally with the administered dose. The maximum serum concentration of hGH released from TransCon hGH was comparable to the levels achieved by the corresponding amount of hGH given as daily injections. The hGH profiles during Week 4

following weekly subcutaneous administration of TransCon hGH or daily subcutaneous administration of Omnitrope® (0.006 mg hGH/kg/day, equivalent to 0.04 mg hGH/kg/week) demonstrated good dose proportionality between TransCon hGH dose groups, with peak serum concentrations of hGH being comparable between dose matched TransCon hGH and daily hGH (0.04 mg hGH/kg/week).

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

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

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

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

Phase 2 study in pediatric patients with GHD

On July 30, 2015, we announced positive top-line results from a six-month Phase 2 study to evaluate the safety and efficacy of once-weekly TransCon hGH in 53 treatment-naïve, pre-pubertal children with GHD. The Phase 2 pediatric study was conducted to investigate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of TransCon hGH in treatment-naïve pre-pubertal children with GHD. The Phase 2 pediatric study enrolled patients from across Europe and North Africa who meet internationally recognized criteria for GHD, including short stature as measured by height and height velocity, two hGH stimulation tests, a bone age evaluation, and IGF-I levels below -1 standard deviation score, or SDS. Published data from clinical trials of growth hormone and growth hormone analogs suggests that our Phase 2 pediatric study patient demographics are comparable to U.S. and E.U. studies of daily and long-acting growth hormone products. The study enrolled 53 patients into the treatment phase and was a 6-month multi-center, randomized, open-label study comparing three dose levels of TransCon hGH (0.14; 0.21; and 0.30 mg hGH/kg/week), administered once per week, to the active control Genotropin (0.21 mg hGH/kg/week), administered as a daily injection. The primary efficacy endpoint is annualized mean height velocity at six months.

Mean annualized height velocities among the three dosing levels administered weekly ranged from 11.9 cm for the 0.14 mg/kg/week dose to 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.

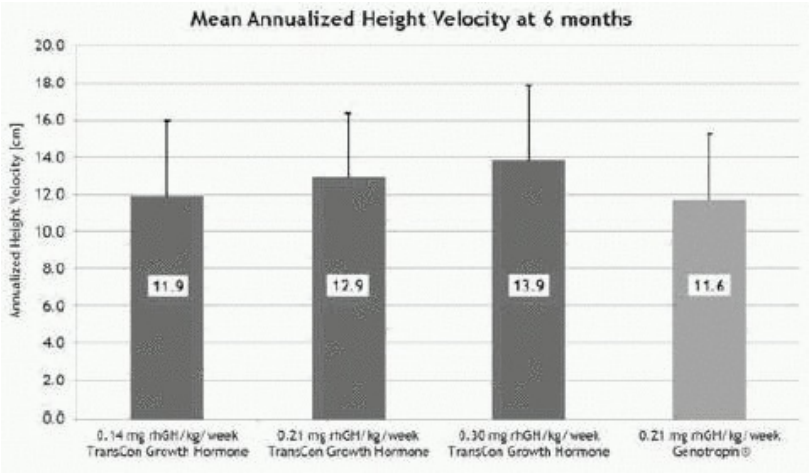


Figure 2. Annualized six-month height velocity (N=53) of three dose-levels of TransCon hGH administered once per week (at doses of 0.14, 0.21 and 0.30 mg hGH/kg/week), against an active control group comprising Genotropin® (0.21 mg hGH/kg/week), administered as injections once per day (0.03 mg hGH/kg) for seven days.

The Phase 2 pediatric study profiled IGF-I levels, the primary biomarker for GHD, during week 13. This profile demonstrated a dose-proportionality in IGF-I levels between the three TransCon hGH doses. The normal range for IGF-I in children varies with age, so IGF-I levels are expressed as IGF-I standard deviation scores, or IGF-I SDS, which enables the comparison of IGF-I responses for children across age ranges. The normal range is defined as IGF-I SDS between -2 and +2 SDS. The mean IGF-I response for all TransCon hGH dose levels were maintained in the normal range. Transient point values of IGF-I SDS > +2 were observed in a small number of patients and only in the high-dose treatment arm. These results are consistent with published data evaluating the effects of comparable doses of daily hGH on IGF-I. There were no reports of safety issues in connection with these transient elevations.

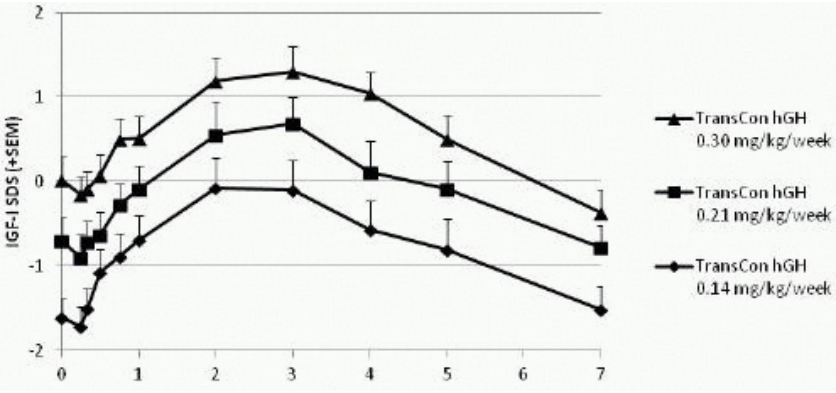


Figure 3. IGF-I profiles during Week 13 following weekly subcutaneous administration of TransCon hGH (at doses of 0.14 mg, 0.21 mg and 0.30 mg hGH/kg/week). Dose dependent IGF-I response observed. Error bars +Standard Error of the Mean.

The Phase 2 pediatric study measured blood levels of hGH released from TransCon hGH and daily hGH during week 13. Consistent with previous clinical studies of TransCon hGH, this profile demonstrated a dose-proportional increase in unmodified growth hormone following administration of the three dose levels of TransCon hGH, and, as illustrated in Figure 4, the maximum blood concentration of unmodified hGH released from TransCon hGH was comparable to the levels achieved by the corresponding amount of hGH given as daily injections.

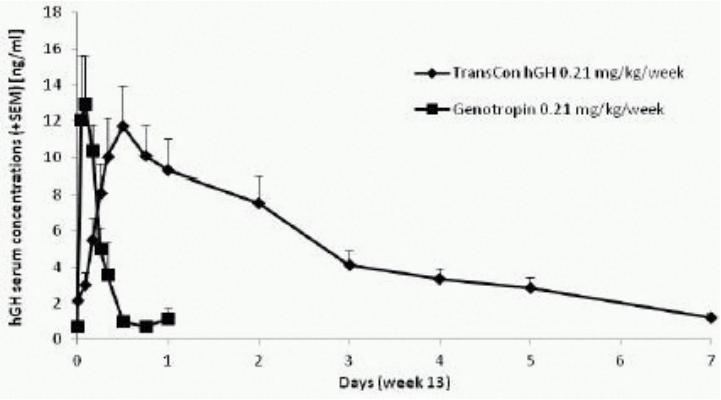


Figure 4. hGH profiles during Week 13 following weekly subcutaneous administration of TransCon hGH (0.21 mg hGH/kg/week) or daily subcutaneous administration of Genotropin® (0.21 mg hGH/kg/week). Error bars +Standard Error of the Mean

The annualized height velocity reported from the December 2014 interim analysis compares favorably in a cross-study comparison with the height velocity reported in a large pharmaco-epidemiological survey known as KIGS—Pfizer International Growth Database. KIGS is a registry that measures real-world outcomes from daily growth hormone therapy, which includes the negative effect of non-compliance on treatment outcomes. We believe that once-weekly TransCon hGH will reduce the burden of daily injections, improving patient compliance and thereby potentially improving treatment outcomes. As demonstrated by the difference in the height velocity between TransCon hGH and the age-matched KIGS historical controls in the figure below, if the efficacy observed for TransCon hGH in the interim analysis is confirmed in longer term studies, it may be possible to improve real-world treatment outcomes by improving compliance with the dosing regimen.

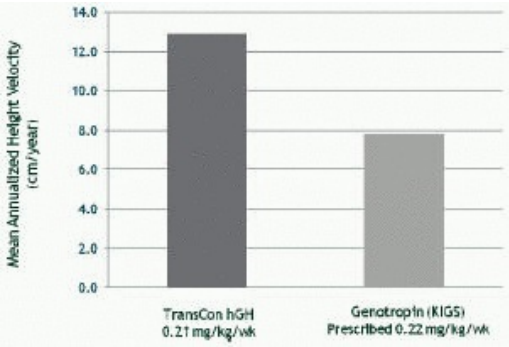


Figure 5. Comparison of annualized six-month height velocity of TransCon hGH to age-matched historical controls that were prescribed daily hGH at a weekly dose of 0.22 mg/kg/week (Ranke et al 2010). This cross-study comparison is a post hoc analysis with no statistical comparison conducted between the two groups.

There were over 1100 injections thus far in our Phase 2 pediatric study. There was one reported case of an inguinal hernia, which has been deemed unlikely to be related to the study drug, and there were no other reports of serious or unexpected adverse events. The adverse events observed were consistent with daily hGH therapy and not different between cohorts. Injection site reactions were generally mild and transient and we observed no incidences of injection site nodule formation or lipoatrophy. TransCon hGH showed low immunogenicity comparable to levels reported for daily hGH therapies, with no neutralizing antibodies.

Development Plans

We plan to schedule an End of Phase 2 meeting with the FDA and the European Medicines Agency, or EMA, to further discuss the design of our Phase 3 clinical program and general regulatory strategy. We plan to propose a single trial with a non-inferiority design compared to daily hGH with a primary endpoint of 12-month mean height velocity. We believe the Phase 3 clinical program will consist of a multi-center, open-label, non-inferiority study comparing the safety and efficacy of a single dose level of once-weekly TransCon hGH to daily hGH in children with growth failure due to GHD. We expect the study to commence in mid-2016 and to consist of approximately 150 treatment naïve pre-pubertal GHD children using inclusion criteria that are similar to those we employed in our Phase 2 pediatric clinical study.

In addition, we are developing a pen device with Medicom Innovation Partner A/S for administration of TransCon hGH that is designed to be easy-to-use in the pediatric population and leverages proven technologies.

We believe an easy-to-use pen device is important for optimal market acceptance, and we are designing the pen to enable small injection volumes and utilize small needles comparable to those used with current daily growth hormone products, which is 30 gauge or finer. To enable ideal storage conditions, TransCon hGH has been designed to be stable at room temperature for at least two years.

As TransCon hGH is a prodrug of an approved drug, we plan to submit a new drug application, or NDA, to the FDA under Section 505(b)(2), which permits companies to rely upon the FDA's previous findings of safety and effectiveness for an approved product. We plan to use Genotropin® as a reference listed drug. We believe this approach offers several benefits, including the potential for approval for several indications included within the reference listed drug's label, based on clinical data from a single pivotal trial of TransCon hGH in pediatric patients with GHD.

We currently retain world-wide commercial rights to TransCon hGH, and will consider forming strategic alliances, creating joint ventures or entering into licensing arrangements with third parties in key geographies where we believe a collaboration partner can aid in the development, regulatory approval and commercialization of TransCon hGH.

TransCon Treprostinil

We are developing TransCon Treprostinil for the treatment of PAH, a life-threatening disease characterized by elevated blood pressure in the pulmonary arteries. According to Medtrack, the worldwide market for PAH therapies exceeded $4 billion in 2014.

Treprostinil, the active agent in United Therapeutics' product Remodulin®, is the leading infused therapy for the treatment of PAH. We are applying our TransCon technology to develop TransCon Treprostinil to be given as a once-daily injection rather than as continuously infused therapy. This improvement in the administration of treprostinil is expected to minimize the limitations of infused treprostinil therapy, such as infusion site pain and the risk of infection. In April 2014, we announced data from the Phase 1 single ascending dose study of TransCon Treprostinil. TransCon Treprostinil produced dose-dependent increases in plasma treprostinil levels in-line with expectations. However, treprostinil-related injection-site tolerability issues did not meet the criteria defined in the target product profile. We are conducting additional research on new product formulations of TransCon Treprostinil and plan to resume clinical development when product improvements to mitigate current limitations have been addressed.

Overview of Pulmonary Arterial Hypertension

PAH is a life-threatening disease characterized by elevated blood pressure in the pulmonary arteries. As the disease worsens, the right side of the heart works harder to pump blood to the lungs and this eventually leads to right heart failure and, ultimately, death. Treatments for PAH aim to reduce symptoms, improve quality of life and slow disease progression. In many cases, improvement in a patient's exercise capacity, as measured by the 6 minute walk distance test, is used as an indicator of therapeutic effect. Mild-to-moderately affected PAH patients can frequently be managed with oral therapies such as PDE-5 inhibitors and endothelin receptor antagonists. Oral or inhaled prostacyclin analog therapy may be added as symptoms worsen. Patients suffering from severe PAH may receive continuously infused prostacyclin analog therapies.

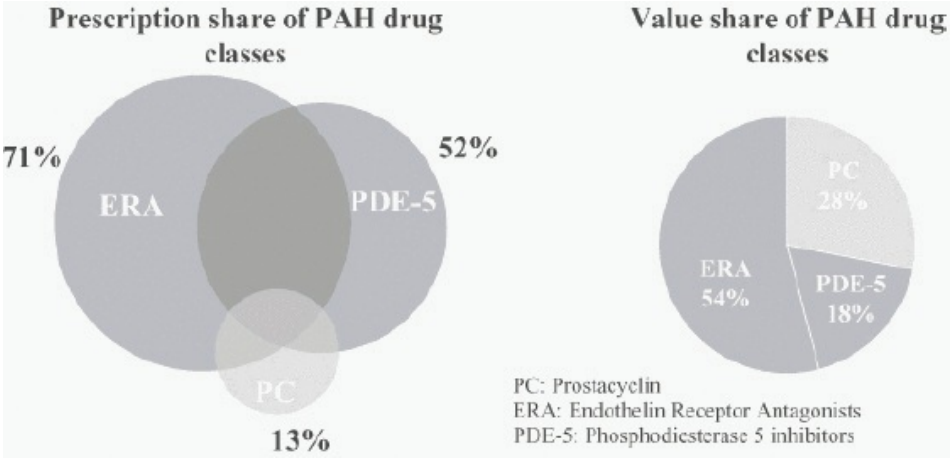


Figure 6. PAH patients frequently receive oral therapies such as PDE-5 inhibitors and endothelin receptor antagonists. As the disease progresses, often a combination therapy is initiated to control symptoms. Oral or inhaled prostacyclin analog therapy may be added as symptoms worsen. Treatment guidelines recommend continuously infused prostacyclin analog therapies for severe PAH. Despite a minority share of PAH prescriptions, the prostacyclin drug class constitutes 28% of the value in the PAH market.

Remodulin® (treprostinil) is the most commonly prescribed infused prostacyclin analog in the United States. Some PAH patients require continuous exposure to Remodulin® and the drug must be administered as either a continuous subcutaneous or intravenous infusion. The utilization of subcutaneous infusion may be limited as a result of infusion site pain and injection site reactions, including redness and swelling, which occurs in the majority of patients. These symptoms can be severe and lead to treatment with narcotics or discontinuation of Remodulin®. These reactions occur as a result of exposure of the subcutaneous tissue to the free active treprostinil. Intravenous Remodulin®, which was developed for and is used in those patients who poorly tolerate the subcutaneous route of administration, can have several safety issues, including infusion line infections, sepsis, arm swelling, tingling sensations, bruising and pain.

We are developing TransCon Treprostinil to provide a safer and more convenient alternative to currently infused forms of Remodulin®, which could enable patients to avoid the localized infusion site pain and site reactions associated with the continuous subcutaneous route of administration, and bloodstream infection risks associated with the central venous catheter used for the continuous intravenous routes of administration. Our target product profile includes the following key attributes:

- Minimal injection site pain: TransCon Treprostinil is designed to be a prodrug which is absorbed into the bloodstream and release unmodified treprostinil at efficacious levels, which is expected to reduce injection site exposure to the free treprostinil
- Continual exposure: slow release of treprostinil from the prodrug should ensure continual exposure and minimizes the risk of fatal rebound PAH that can be experienced with mechanical pump failures
- No risk of sepsis: risk of sepsis associated with intravenous infusions eliminated
- Pen device: compatible with easy to use pen device for once-daily self-administration

Market Opportunity

According to Medtrack, the worldwide market for PAH therapies exceeded $4 billion in 2014 and the worldwide market for prostacyclin-based PAH treatments exceeded $1.2 billion in 2013. It is estimated that PAH affects between 100,000 and 200,000 individuals worldwide. Although awareness of PAH continues to grow and the number of people diagnosed with the disease is increasing, PAH is still considered an orphan disease. Due to the low prevalence of the disease and the complexity of diagnosing PAH, only a small fraction of affected patients are currently being treated. Easier, less invasive methods of diagnosing PAH are under investigation, and, if successful, more patients could be diagnosed at an earlier stage of the disease, increasing the number of patients seeking treatment.

Limitations of Current Prostacyclin Therapies

Continuous exposure to prostacyclin is well-established as the gold-standard of treatment for late-stage PAH and "rescue therapy" for deteriorating PAH patients. However, despite current treatment guidelines recommending prostacyclin analog therapy as mono or combination therapy in patients with PAH, clinicians frequently delay the initiation of prostacyclin therapy. Data from the largest multicenter, observational registry of PAH patients in the United States, REVEAL, demonstrate that a substantial number of advanced patients were not being treated as aggressively as current guidelines recommend, *i.e.*, with intravenous prostacyclin analog and/or combination therapy. Approximately half of the PAH patients that died during the observation period were not treated with prostacyclin analogs at the time of death.

Due to the significant shortcomings of continuous prostacyclin analog infusion, alternative delivery approaches have been explored, including inhaled and oral prostacyclin analogs and an implantable continuous infusion pump. However, these approaches carry limitations specific to their respective delivery method.

Conventional Infused Prostacyclin Analog Therapy

Due to the natural progression of PAH, many patients eventually progress to requiring prostacyclin analog infusion, which has become well established in clinical practice as the standard of treatment for severe PAH patients. There are three branded infused prostacyclins on the U.S. market: Remodulin® (treprostinil) from United Therapeutics, Flolan® (epoprostenol) from GlaxoSmithKline, and Veletri® (epoprostenol) from Actelion. In 2008, Teva Pharmaceuticals launched a generic version of Flolan, epoprostenol.

Intravenous prostacyclin analogs are delivered continuously through a surgically implanted central venous catheter. These catheters are inserted into major veins close to the heart to maximize drug delivery to the lungs and blood vessels. Typically a pump device containing a reservoir for medication refilling is connected to the catheter and must be worn or carried externally for years after diagnosis. Patients or their families are required to prepare the drug refill solution aseptically in a specialized designated clean area of their home every 24 to 48 hours, followed by refilling of the infusion pump. If strict aseptic preparation procedures are not followed, patients receiving intravenously infused prostacyclin may face sepsis, a life threatening bloodstream infection.

As an alternative to intravenous infusion of prostacyclins, patients can receive subcutaneous infusions. However, subcutaneously infused prostacyclin therapy can cause infusion site reactions. In the pivotal study of Remodulin® 85% of patients had infusion site pain and 32% of patients required narcotics to alleviate the pain associated with administration.

Inhaled Prostacyclin Analogs

Two prostacyclin analogs, Actelion's Ventavis® (iloprost), and United Therapeutics' Tyvaso® (treprostinil), are formulated for inhaled delivery. Due to the short half-life of prostacyclin analogues in the body, PAH patients must inhale prostacyclins four to nine times per day using a nebulizer. Preparation of the nebulizer and drug product, and the actual inhalation session, require considerable time and resources which are burdensome for patients. The amount of prostacyclin analog delivered through inhaled systems is intermittent and with a lower cumulative dose as compared to the cumulative dose received with continuous infusion therapy. This results in a reduction in overall systemic exposure of prostacyclin.

Oral Prostacyclin Receptor Agonists

In December 2013, United Therapeutics received FDA approval for Orenitram™ (treprostinil) Extended-Release Tablets. When used as monotherapy, the effect of Orenitram™ on exercise is small and Orenitram™ has not yet been shown to be efficacious in combination with other approved PAH therapies. Gastro-intestinal side effects resulting from treatment with Orenitram™ can be dose limiting, and may prevent titration to an effective dose level. In December 2015, Actelion received FDA approval for Uptravi (selexipag), an oral prostacyclin receptor agonist.

Alternative Infusion Pumps

United Therapeutics is supporting studies of treprostinil administered by an implantable pump, in partnership with Medtronic. The SynchroMed II Remodulin® pump will be surgically implanted in the abdomen of patients and re-filled by transdermal injection into an injection port. As the pump requires surgery for implantation, it is an invasive intervention and risks associated with the implantation surgery in an already fragile PAH patient base may affect adoption rates. In December 2014, a premarket approval application was submitted to the FDA for the use of Medtronic's Implantable pump with Remodulin®. In April 2015, the FDA filed a consent decree requiring Medtronic to stop manufacturing, designing and distributing SynchroMed II implantable infusion pump systems, except in limited circumstances, citing violation of the quality system regulation for medical devices. We understand United Therapeutics is currently assessing the impact of this consent decree on the program to develop Remodulin Implantable System.

In December 2014, United Therapeutics entered into an exclusive agreement with DEKA Research & Development Corp. (DEKA) to develop a pre-filled, semi-disposable pump system for subcutaneous delivery of Remodulin.

Our Solution: TransCon Treprostinil

Our TransCon Treprostinil is designed to be a once-daily self-administered subcutaneous injection of treprostinil, intended to offer the same efficacy as continuously-infused prostacyclin analogs, but with a safer and more convenient route of administration, with reduced infusion site pain/reaction and bloodstream infection risks associated with the continuous subcutaneous and intravenous routes of administration of treprostinil, respectively.

TransCon Treprostinil is a prodrug, designed to be inactive at injection, thus reducing the potential for injection site reactions. As the prodrug is absorbed into the bloodstream, it behaves as a circulating depot releasing free treprostinil, via predictable cleaving of the TransCon linker, at levels comparable to continuous infusion. Our TransCon prodrug technology extends the half-life of treprostinil in the body to ensure continuous exposure. We believe the long half-life may minimize the risk of potentially fatal rebound PAH, which has been reported following interruption of continuously infused prostacyclins due to infusion pump or catheter malfunction and patient error.

TransCon Treprostinil is expected to require minimal preparation. The PAH patient, or their caregiver, will administer a single subcutaneous injection once each day, meaningfully decreasing the burden on patients compared to the administration requirements of continuous infusion options. Furthermore, as no indwelling catheters are needed, there is no requirement for implantation surgery and no risk of potentially fatal infections or complications due to a central venous catheter.

We believe that a safer and better tolerated prostacyclin analog therapy with a more convenient administration profile can improve treatment outcomes and facilitate faster adoption of parenteral prostacyclin analog therapy. We believe that patients currently delaying infused prostacyclin therapy due to fear of adverse effects and the high treatment burden, as well as less severe patients inadequately controlled on oral therapy, can benefit from receiving TransCon Treprostinil. The potential for TransCon Treprostinil to penetrate non-U.S. markets may present another significant opportunity for the product. Historically, non-U.S. markets have seen lower penetration rates of inhaled and infused prostacyclin analogs and it is possible that the potential for the improved safety and tolerability features of TransCon Treprostinil may encourage higher levels of prostacyclin analog use in these markets.

Development of TransCon Treprostinil

In April 2015, we announced data from the Phase 1 single ascending dose study of TransCon Treprostinil. TransCon Treprostinil produced dose-dependent increases in plasma treprostinil levels in-line with expectations. However, treprostinil-related injection-site tolerability issues did not meet the criteria defined in the target product profile. We are conducting additional research on new product formulations of TransCon Treprostinil and plan to resume clinical development when product improvements to mitigate current limitations have been addressed.

As TransCon Treprostinil is a prodrug of treprostinil, we believe that we are eligible to pursue a Section 505(b)(2) regulatory strategy and rely upon the FDA's previous findings of safety and effectiveness for treprostinil. Depending upon the outcome of future clinical studies, we may further propose to the FDA that we pursue a Section 505(b)(2) regulatory strategy based on demonstrating bioequivalence of TransCon Treprostinil to Remodulin®. If the FDA agrees to our proposed Section 505(b)(2) regulatory path, the development timelines for TransCon Treprostinil may be expedited compared to conventional drug approvals.

Former Strategic Collaboration with United Therapeutics

In September 2012, we entered into a collaboration agreement with United Therapeutics under which we granted United Therapeutics a license to research, develop, make and commercialize products based on the TransCon technology and prostacyclin analogs, and later expanded the license to include the drug beraprost. In October 2014, we and United Therapeutics terminated the collaboration agreement, mutually released each other from claims and United Therapeutics transferred the TransCon Treprostinil program, including the IND, to us.

TransCon Peptides

Overview and Market Opportunities

Together with our collaboration partner, Sanofi, we are developing TransCon Peptides for the treatment of diabetes, a major cause of morbidity and mortality across the world. The current standard of care for diabetes often includes daily injections. Compliance and adherence to such regimens are poor due to the burden of daily injections. According to the WHO, diabetes is a global epidemic with 347 million people worldwide having diabetes. The diabetes market is expected to increase due in part to increasing obesity rates, and currently supports 10 major products with combined sales in 2014 exceeding $30 billion, according to Medtrack. More than half of these are peptidic drugs requiring daily injections.

Our Solution: TransCon Peptides

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

Strategic Collaboration with Sanofi

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

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

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

TransCon Ranibizumab

Overview and Market Opportunity

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

In 2014, the worldwide sales of anti-VEGF ophthalmology drugs exceeded $7 billion, comprised primarily of Lucentis® and a recent entrant Eylea® from Regeneron Pharmaceuticals, Inc./Bayer AG. There is high interest in developing longer acting therapies for intravitreal drug delivery in order to reduce the burdensome intravitreal injections required by the current standard of care. In this market, patient compliance remains a challenge and patients and physicians sometimes accept less than optimal dosing frequencies for certain individuals. A reliable and consistent method to achieve visual gains with up to half-yearly dosing represents a potential major breakthrough and could quickly become the new standard of care.

Limitations of Established Long-acting Intravitreal Technologies

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

Our Solution: TransCon Ranibizumab

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

TransCon Ranibizumab is a novel prodrug designed to support up to half-yearly administration frequency, and to provide the same or improved efficacy compared to current intravitreal anti-VEGF injections.

Development Plans

Genentech is currently conducting preclinical studies to evaluate the safety of various TransCon prodrug candidates for intravitreal administration.

Strategic Collaboration with Genentech

In July 2013, we entered into a strategic collaboration agreement with Genentech and Roche, referred to collectively as Genentech, under which we granted Genentech an exclusive, worldwide royalty-bearing license to make, use and commercialize products based on the TransCon technology and any therapeutic or prophylactic compound, other than GLP-1, glucagon and/or insulin, for the treatment and/or prevention of any disease, condition or disorder of the eye, other than diabetic retinopathy. We also granted to Genentech a worldwide, non-exclusive, royalty-bearing license to make, use and commercialize such products to treat diabetic retinopathy. Under the agreement, we are prohibited from conducting, or granting rights to third parties to conduct in connection with any

generic version of licensed products, any research, development or commercialization of the licensed intellectual property and technology rights for use in treatment or prevention of any ophthalmic condition or disorder, or for diabetic retinopathy, subject to certain exceptions and conditions. In addition, during the term of the agreement, we are prohibited from developing or commercializing any licensed product that contains a compound that is either proprietary to Genentech and that is the subject of active research and development efforts or subject to payment obligations under the agreement, or for a specified time period, that is one of a group of compounds commercialized and designated by Genentech, in each case for uses other than the treatment or prevention of any ophthalmic condition or disorder, or diabetic retinopathy. Under the agreement, we own any inventions made by either party solely relating to our TransCon technology under the collaboration. Further, we received a non-exclusive, royalty-free license (with the right to grant sublicenses) under Genentech's rights in any process invention or joint invention generated in connection with the collaboration, to make, use or sell products (other than glucagon product, GLP-1 product and insulin product) outside the field of treatment and/or prevention of any disease, condition or disorder of the eye.

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

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

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 staff 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 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 technology. 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 technology. We also expect that technological developments will occur at a rapid rate and that competition is likely to intensify as various enhanced delivery and sustained released technologies may achieve similar advantages.

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

Intellectual Property

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

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

As of December 31, 2015, we own a total of 37 patent families, of which 8 are currently in their priority year or international phase and we own several granted patents in the United States (11), Europe (2), Australia (10), Canada (1), China (6), Israel (4), New Zealand (2), Japan (4), Mexico (5), Singapore (3), Russia (1) and South Africa (8) and have more than 200 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, 2015 are summarized below and the expected expiration dates included in the summary below do not give effect to patent term extensions that may be available.

TransCon hGH

Our patent portfolio related to TransCon hGH includes six patent families relating to different aspects of TransCon hGH. 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, 2015, this patent family included patents granted in Europe and the United States and a patent application in Europe. We expect any patents granted in this patent family to expire in October 2024.

The second of these patent families is a composition of matter patent family directed to a TransCon linker used in TransCon hGH. As of December 31, 2015, this patent family included patents granted in the United States, Australia, Japan and Mexico and included patent applications in Europe, the United States, Brazil and Canada. 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, 2015, this patent family included patents granted in Australia, China, Israel, Mexico, Russia and South Africa and included patent applications in Europe, the United States, Brazil, Canada, India, Japan, Mexico and Russia. We expect any patents granted in this patent family to expire in April 2029.

The fourth of these patent families is a composition of matter patent family directed to specific dry pharmaceutical compositions comprising TransCon hGH. As of December 31, 2015, this patent family included patents granted in Australia, Singapore and South Africa and included patent applications in Europe, the United States, Brazil, Canada, China, Israel, India, Mexico and Russia. 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, 2015, this patent family consists of an international patent application. 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 regiment for long-acting growth hormone formulations. As of December 31, 2015, this patent family consists of an international patent application. We expect any patents granted in this patent family to expire in November 2035.

TransCon Treprostinil

Our patent portfolio related to TransCon Treprostinil currently includes two patent families. The first patent family is a composition of matter patent family directed to the TransCon Treprostinil product concept. As of December 31, 2015, this patent family included patent applications in Europe, the United States, Australia, Brazil, Canada, China, Israel, India, Japan, South Korea, Mexico, Singapore and South Africa. We expect any patents granted in this patent family to expire in August 2032. The second patent family is also a composition of matter patent family directed to the lead candidate structure including the actual product structure. As of December 31, 2014, this patent family included patent applications in Europe, the United States, Australia, Brazil, Canada, China, Israel, India, Japan, South Korea, Mexico, Singapore and South Africa. We expect any patents granted in this patent family to expire in August 2032.

Field of Diabetes

In the field of diabetes, our patent portfolio related to TransCon product candidates under development with our collaboration partner, Sanofi, include four product-specific patent families previously sold to Sanofi and four technology-patent families owned by us and out-licensed to Sanofi. The first patent family owned by us is referred to as our AP006 patent family and this patent family is a composition of matter patent family broadly directed to one of our TransCon linkers. This patent family relates to our TransCon technologies and product candidates in the diabetes and ocular fields, among others. As of December 31, 2015, this patent family included patents granted in the United States, Australia, China, Israel, Japan, Mexico and South Africa and included patent applications in Europe, the United States, the United Arab Emirates, Brazil, Canada, India, Mexico and Russia. We expect any patents granted in this patent family to expire in January 2029.

The second patent family owned by us is referred to as our AP003 patent family and this patent family is a combination of a composition of matter and a process patent family directed to particular TransCon hydrogels. This patent family relates to our TransCon technologies and product candidates in the diabetes and ocular fields, among others. As of December 31, 2015, this patent family included two patents granted in the United States and included patent applications in Europe and the United States. We expect any patents granted in this patent family to expire in October 2024.

The third patent family is a composition of matter patent family also directed to a PEG-based hydrogel comprising certain backbone and crosslinker structures. As of December 31, 2015, this patent family included patents granted in Australia, China, New Zealand, Singapore and South Africa, and included patent applications in Europe, the United States, Brazil, Canada, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, Russia and Thailand. We expect any patents granted in this patent family to expire in July 2030.

The third patent family owned by us is referred to as our AP019 patent family and this patent family is a process patent family directed to the sterilization of TransCon hydrogels. This patent family relates to our TransCon technology and product candidates in the diabetes and ocular fields, among others. As of December 31, 2015, this patent family included patents granted in the United States, Australia, China, Israel, Mexico, New Zealand, Singapore and South Africa, and included patent applications in Europe, the United States, Brazil, Canada, Indonesia, India, Japan, South Korea, Mexico, Malaysia, Russia and Thailand. We expect any patents granted in this patent family to expire in October 2030.

Ocular Field

Our patent portfolio related to our work in the ocular field includes seven patent families, three of which are our AP003, AP006 and AP019 patent families which are described above and two of these patent families are exclusively out-licensed to our collaboration partner, Genentech. Other than the AP003, AP006 and AP019 patent families described above, our patent families related to our work in the ocular fields are described in this section below.

The first patent family is exclusively out-licensed to Genentech and is a composition of matter patent family directed to the general concept of using hydrogel prodrugs for the treatment of ocular diseases. As of December 31, 2015, this patent family included one granted patent in South Africa and included patent applications in Europe, the United States, Australia, Brazil, Canada, China, Israel, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia and Singapore. We expect any patents granted in this patent family to expire in October 2032.

The second patent family exclusively out-licensed to Genentech is a composition of matter patent family directed to a broad class of TransCon prodrugs of vascular endothelial growth factor neutralizing drugs. As of December 31, 2015, this patent family included one granted patent in South Africa and included patent applications in Europe, the United States, Australia, Brazil, Canada, China, Israel, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia and Singapore. We expect any patents granted in this patent family to expire in October 2033. The third patent family not described above is a process patent family also comprising product-by-process claims directed to a TransCon hydrogel especially applicable to protein drugs and product candidates. As of December 31, 2015, this patent family included patent applications in Europe, the United States, Australia, Brazil, Canada, China, Israel, India, Japan, Mexico, Malaysia, Russia, Singapore and South Africa. We expect any patents granted in this patent family to expire in October 2033. The fourth patent family not described above is a composition of matter patent family directed to inventions useful in the synthesis of certain prodrugs generally related to protein conjugates. As of December 31, 2015, this patent family is in international phase claiming priority of a European patent application. We expect any patents granted in this patent family to expire in October 2034.

TransCon Technology

Our patent portfolio also includes patents and patent applications generally relating to our TransCon technology, including TransCon linkers, TransCon carriers and certain soluble conjugates. We own an aggregate of eleven patent families relating to TransCon linkers, the material components of which are described above. We own an aggregate of eight 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, 2015, this patent family included patents in Europe and the United States and patent applications in Europe. We expect any patents granted in this patent family to expire in October 2024.

Laws and Regulations Regarding Patent Terms

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent term may be shortened if a patent is terminally disclaimed over another patent or as a result of 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.

Manufacturing

As we do not maintain the capability to manufacture finished drug products, we utilize contract manufacturers to manufacture our proprietary drug candidates. We source starting materials for our manufacturing activities from one or more suppliers. For the starting materials necessary for our proprietary drug candidate development, we have agreements for the supply of such drug components 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 APIs required for later phases of clinical development and eventual commercialization for us under all applicable laws and regulations.

We have analytical and process development capabilities in our own facility. We generally perform drug candidate development, analytical and process development for our proprietary drug candidates internally, and manufacture the drugs necessary to conduct the non-GLP preclinical studies of our investigational product candidates. We occasionally outsource the production of research and development material. Occasionally our collaboration partners may conduct production of research and development material for products in their respective field. Each of our collaboration partners have granted us rights that enable us to freely commercialize all improvements to the TransCon Prodrug technology and manufacturing process developed by our collaboration partners outside of the field identified in their respective collaboration agreements.

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 product for clinical trial use in compliance with cGMP and applicable local regulations. cGMP regulations include requirements relating to organization of personnel; buildings and facilities; equipment; control of components and drug product containers and closures; production and process controls; packaging and labeling controls; holding and distribution; laboratory controls; records and reports; and returned or salvaged products. The manufacturing facilities for our products must be in compliance with cGMP requirements, and for device and device components, the Quality System Regulation, or QSR, requirements, before any product is approved. We ensure cGMP compliance of our suppliers through regular

quality inspections performed by our Quality Assurance group. Our third-party manufacturers may also be subject to periodic inspections of facilities by the FDA, the Competent Authorities of the Member States of the European Economic Area (EEA, comprising the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein), and other authorities, including reviews of procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. These actions could have a material impact on the availability of our products. In addition, contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

We also contract with additional third parties for the filling, labeling, packaging, testing, storage and distribution of our investigational drug products. 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.

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. Our product candidates must be approved by the FDA through the NDA process before they may be legally promoted in the United States and 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 its implementing regulations, and other federal, state, and local regulatory authorities. The FDCA and its 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, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug 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 product for each indication;
- submission to the FDA of an NDA;
- 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 identity, strength, quality and purity; and
- FDA review and approval of the NDA.

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

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective and a clinical trial proposed in the IND may begin 30 days after the FDA receives the IND, unless during this 30-day waiting period, the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of the investigational new drug 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. In addition, an IRB at each institution

participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their www.clinicaltrials.gov website.

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

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

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical studies, 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.

Marketing Approval

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

In addition, under the Pediatric Research Equity Act of 2003 as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each

pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

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

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

Before approving an NDA, 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, 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 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 if the study was conducted in accordance with GCP requirements and the FDA is able to validate the data through an on-site inspection, if deemed necessary. Although the FDA generally requests that marketing applications be supported by some data from domestic clinical studies, the FDA may accept foreign data as the sole basis for marketing approval if (1) the foreign data are applicable to the U.S. population and U.S. medical practice, (2) the studies were performed by clinical investigators with recognized competence, and (3) the data may be considered valid without the need for an on-site inspection or, if the FDA considers the inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

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

After evaluating the NDA 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 generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

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

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA and other government authorities, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

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

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

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

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

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

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

Hatch-Waxman Amendments and Exclusivity

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an abbreviated new drug application, or ANDA, seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired. Specifically, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

Pediatric Exclusivity

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

Foreign Regulation

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

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

Centralized Procedure

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

National Authorization Procedures

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

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

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

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

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

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

Other Healthcare Laws

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

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

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

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

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

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act imposed, among other things, new annual reporting requirements for covered manufacturers for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures." Covered manufacturers were required to begin collecting data on August 1, 2013 and submit reports on aggregate payment data to the government for the first reporting period (August 1, 2013 – December 31, 2013) by March 31, 2014, and required to report detailed payment data for the first reporting period and submit legal attestation to the completeness and accuracy of such data by June 30, 2014. Thereafter, covered manufacturers must submit reports by the 90th day of each subsequent calendar year. In addition, certain states require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices, and/or tracking and reporting of gifts, compensation and other remuneration or items of value provided to physicians and other healthcare professionals and entities.

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

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

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

Coverage and Reimbursement

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

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

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

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. By way of example, in the United States, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for outpatient drug purchases by those covered by Medicare under a new Part D and introduced a new reimbursement methodology based on average sales prices for Medicare Part B physician-administered drugs, including drugs currently on the market used by physicians to treat the clinical indications for which we are currently seeking FDA approval and likely our product candidates, if approved. As a result of this legislation and the expansion of federal coverage of drug products, there is additional pressure to contain and reduce costs. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. These cost reduction initiatives and other provisions of the MMA could decrease the coverage and reimbursement that we receive for any approved products, and could seriously harm our business.

In addition, in March 2010, the Affordable Care Act was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans, imposed mandatory discounts for certain Medicare Part D beneficiaries, subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs and imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices.

On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Tax Payer Relief Act was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

C. Organizational Structure

Certain of our operations are conducted through our subsidiaries and we have the following subsidiaries: Ascendis Pharma GmbH (Germany), Ascendis Pharma, Inc. (Delaware, United States), Ascendis Pharma, Ophthalmology Division A/S (Denmark), Ascendis Pharma, Endocrinology Division A/S (Denmark), Ascendis Pharma, Osteoarthritis Division A/S (Denmark) and Ascendis Pharma, Circulatory Diseases Division A/S (Denmark). These subsidiaries are also set forth in Exhibit 8.1 to this annual report.

D. Property, Plant and Equipment

In January 2016, we moved our headquarters to Tuborg Boulevard 5, DK-2900 Hellerup, Denmark, where we lease approximately 1,328 square meters of office space. The lease commenced on December 1, 2015 and can be terminated at the earliest on (1) November 30, 2022 by our option, and (2) November 30, 2028 by the landlord's option. The lease provides for an annual base rent of approximately DKK 2,205,100, or €295,487 (based on the exchange rate reported by the European Central Bank on December 31, 2015). We maintain a research facility in Heidelberg, Germany, where we lease 1,495 square meters of office and laboratory space. The lease for our Heidelberg facility expires January 31, 2017. We have also leased in Palo Alto, California (1) 170 square meters of office space pursuant to a lease that expires May 30, 2018 and (2) 465 square meters of office space pursuant to a lease that expires March 15, 2021, which may be extended at our option for three years subject to certain conditions. We believe that our existing facilities are adequate for our near-term needs. We believe that suitable additional or alternative space would be available if required in the future on commercially reasonable terms.

Item 4A *Unresolved Staff Comments*

Not applicable.

Item 5 *Operating and Financial Review and Prospects*

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

A. Operating Results

Overview

We are a clinical stage biopharmaceutical company applying our TransCon technology to develop a pipeline of long-acting prodrug therapies with best-in-class profiles to address large markets with significant unmet medical needs. We are developing our lead product candidate, TransCon human growth hormone, or TransCon hGH, for once-weekly administration to treat growth hormone deficiency, or GHD, and other indications. We have successfully completed Phase 2 studies of TransCon hGH in children and adults with GHD. In July 2015, we announced positive top-line results from a six-month Phase 2 study to evaluate the safety and efficacy of once-weekly TransCon hGH in 53 treatment-naïve, pre-pubertal children with GHD. Using our TransCon technology, we have established a new paradigm that combines the benefits of conventional prodrug and sustained release technologies, and is broadly applicable to proteins, peptides and small molecules. In addition to TransCon hGH, we have developed a pipeline of long-acting prodrug product candidates such as TransCon Treprostinil for the treatment of pulmonary arterial hypertension, or PAH, TransCon Peptides, for the treatment of diabetes, partnered with Sanofi, and TransCon Ranibizumab, in the field of ophthalmology, partnered with Genentech.

We commenced operations in December 2007 when we acquired Complex Biosystems GmbH, the company that invented the TransCon technology. Since we commenced operations in 2007, we have devoted substantially all of our efforts to developing our product candidates, including conducting preclinical studies and clinical trials and providing general and administrative support for these operations. We do not have any approved products and have never generated any revenue from product sales. Since our inception through December 31, 2015, we have funded our operations through the sale of €186.6 million of our preference shares, ordinary shares and convertible debt securities, including our IPO and exercise of warrants, and we have received aggregate gross proceeds of approximately €73.3 million from collaboration partners for up-front technology licensing fees, assignment of certain intellectual property rights and for services rendered under those agreements.

We had a net loss of €32.9 million for the year ended December 31, 2015 compared to a net loss of €9.7 million for the year ended December 31, 2014, and a net profit of €4.1 million for the year ended December 31, 2013. Our total equity was €120.3 million as of December 31, 2015 compared to €45.8 million as of December 31, 2014. We have not generated royalties or revenues from product sales, and do not expect to generate royalties or revenues from product sales prior to regulatory approval of any of our product candidates.

In November 2014, we issued 6,133,832 preference D shares to new and existing investors at a price of €8.0602 ($9.7818) per share for aggregate gross proceeds of approximately €48 million ($60 million). In February 2015, we closed our initial public offering of 6,900,000 American Depositary Shares on the NASDAQ Global Select Market. Each ADS represents one ordinary share at a price to the public of $18.00 per ADS, generating gross proceeds to the Company of $124.2 million (€109.8 million at the date of transaction). We believe that at some point in the future we will need substantial additional capital to support our operating activities and adequate funding may not be available to us on acceptable terms, or at all.

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

- pursue our ongoing and planned clinical development of TransCon hGH for the treatment of pediatric GHD;
- continue to invest in our TransCon technology, including our intellectual property, our lab, clinical and commercial scale manufacturing capabilities and our methods and know-how;
- hire additional personnel, particularly in our research and development, clinical supply and quality control groups;
- add operational, financial and management information systems and related finance and compliance personnel; and
- continue to operate as a public company.

Collaboration Agreements

Sanofi

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

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

Genentech

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

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

United Therapeutics

In September 2012, we entered into a collaboration agreement with United Therapeutics under which we granted United Therapeutics an exclusive, worldwide, royalty-bearing license to research, develop, make and commercialize products based on the TransCon technology and prostacyclin analogs, for the treatment, amelioration and prevention of pulmonary hypertension in humans. As consideration, we received a non-refundable, up-front technology license fee of $15 million (€11.7 million). In July 2013, the agreement was amended to include within the scope of this exclusive license products based on the TransCon technology and beraprost, another prostacyclin analog, for the same applications. On June 30, 2014, we received a notice from United Therapeutics informing us of its intent to terminate the collaboration agreement for convenience. In October 2014, we and United Therapeutics terminated the collaboration agreement, mutually released each other from claims and United Therapeutics transferred the TransCon Treprostinil program, including the IND, to us.

Financial Operations Overview

Revenue

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

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

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

Research and Development Costs

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

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

We incur various external expenses under our collaboration agreements for material and services consumed in the development of our partnered product candidates. Under our collaboration agreements, our collaboration partners reimburse us for these external expenses. We recognize these reimbursements as a reduction of research and development costs. External expenses that are not reimbursed are recognized as research and development costs in the period in which they are incurred.

Government grants are recognized when there is reasonable assurance that the conditions underlying the grant have been met and that the grant will be received. We did not receive any government grants in 2015 or 2014. In 2013, we received grants from the German Bundesministerium for development activities related to early stage research applying our TransCon technology to various therapeutic compounds and disease categories. Government grants to cover research and development costs incurred are recognized as a reduction of research and development costs proportionally over the periods during which the related research and development expenses are incurred.

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

For the year ended December 31, 2015, we incurred direct and indirect research and development costs of €26.5 million and €14.0 million, respectively, compared to €9.3 million and €10.4 million for the year ended December 31, 2014 and €4.3 million and €8.4 million, respectively, for the year ended December 31, 2013.

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

We expect our research and development costs to increase in the future as we continue development of our product candidates, conduct our development activities under our collaboration agreements with Sanofi and Genentech, and advance our discovery and research projects into preclinical development.

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

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

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

General and Administrative Expenses

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

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

Finance Income and Finance Expenses

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

Results of Operations

Comparison of the years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,		
	2015	2014	2013
	(EUR'000)	(EUR'000)	(EUR'000)
Revenue	8,118	13,983	20,408
Research and development costs	(40,528)	(19,698)	(12,713)
General and administrative expenses	(9,415)	(6,274)	(2,416)
Operating profit / (loss)	**(41,825)**	**(11,989)**	**5,279**
Finance income	11,048	1,877	158
Finance expenses	(2,797)	(228)	(732)
Profit / (loss) before tax	**(33,574)**	**(10,340)**	**4,705**
Tax on profit / (loss) for the year	652	682	(626)
Net profit / (loss) for the year	**(32,922)**	**(9,658)**	**4,079**

Revenue

The following table summarizes our revenue for the years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,		
	2015 (EUR'000)	2014 (EUR'000)	2013 (EUR'000)
Revenue from the rendering of services	3,192	6,074	4,161
License income	4,926	7,909	16,247
Total revenue	**8,118**	**13,983**	**20,408**

Revenue for the year ended December 31, 2015 was €8.1 million, a decrease of €5.9 million, or 42%, compared to €14.0 million for the year ended December 31, 2014. This change was primarily driven by a decrease of €3.2 million in revenue from our collaboration with United Therapeutics as a result of the collaboration ending at June 30, 2014. Revenue from our collaboration with Sanofi decreased by €2.5 million due to fewer services rendered by us under our collaboration, whereas revenue from our collaboration with Genentech decreased by €0.2 million compared to the same period in 2014.

Revenue for the year ended December 31, 2014 was €14.0 million, a decrease of €6.4 million, or 31%, compared to €20.4 million for the year ended December 31, 2013. This change was driven by a decrease in revenue from our Sanofi collaboration of €6.5 million which resulted from the completion of the period over which we recognized the original upfront payment under the Sanofi collaboration agreement as revenue. Revenue from our collaboration with United Therapeutics decreased by €4.2 million for the year ended December 31, 2014 as compared to the year ended December 31, 2013 due to fewer services rendered by us to United Therapeutics and due to the initial collaboration period ending at June 30, 2014. These decreases were partly offset by an increase in revenue from our collaboration with Genentech of €4.3 million. The collaboration with Genentech was initiated in July 2013, and accordingly, only two quarters of revenue were recognized from this collaboration during the year ended December 31, 2013.

As of December 31, 2015, we had deferred income of €3.1 million arising from collaboration agreements compared to €7.9 million and €17.5 million as of December 31, 2014 and 2013, respectively. This deferred income will be recognized as revenue as we and our collaboration partners advance the projects that are subject to our collaborations.

Research and Development Costs

Research and development costs were €40.5 million for the year ended December 31, 2015, an increase of €20.8 million, or 106%, compared to €19.7 million for the year ended December 31, 2014. This change was primarily attributable to an increase of €16.6 million in external costs associated with our Phase 2 TransCon hGH pediatric study, manufacturing costs and preparation for our Phase 3 study, and continued development of our pen device. External costs associated with our other proprietary product candidates increased by €1.7 million, primarily related to our TransCon Treprostinil project, which we assumed after termination of our collaboration with United Therapeutics in 2014. Personnel costs increased by €1.2 million and recruiting costs increased by €0.7 million due to an increase in the number of employees in research and development functions. General costs such as rent and facility costs, supplies, and consultancy services allocated to research and development increased by €0.6 million. Research and development costs included non-cash share-based payment of €0.7 million for the year ended December 31, 2015, compared to €0.3 million for the year ended December 31, 2014.

Research and development costs were €19.7 million for the year ended December 31, 2014, an increase of €7.0 million, or 55%, compared to €12.7 million for the year ended December 31, 2013. This change was primarily attributable to an increase of €4.9 million in external costs associated with our Phase 2 TransCon hGH pediatric study and costs related to protecting and maintaining our intellectual property rights. Personnel costs increased by €1.0 million due to an increase in the number of employees in research and development functions. General costs such as rent and facility costs, laboratory supplies and consultancy services allocated to research and development increased by €0.7 million. We received €0.4 million in grants from the German Bundesministerium in the year ended December 31, 2013, whereas no grants were received during the year ended December 31, 2014. Grants received during the year ended December 31, 2013 were offset against the research and development costs incurred during 2013. Research and development costs included non-cash share-based payment of €0.3 million for the year ended December 31, 2014 and €0.5 million for the year ended December 31, 2013.

General and Administrative Expenses

General and administrative expenses were €9.4 million for the year ended December 31, 2015, an increase of €3.1 million, or 50%, compared to €6.3 million for the year ended December 31, 2014. Our overhead expenses are allocated to general and administrative and research and development functions based on the proportion of general and administrative to research and development employees. This increase is primarily due to an increase in personnel costs of €1.9 million for additional administrative personnel and more resources being allocated to general and administrative functions, and increases in other costs such as investor relations activities, facility costs, traveling and insurance totaling €1.2 million reflecting the growth of the organization and the increasing requirements of operating as a publicly traded company. General and administrative expenses included non-cash share-based payment of €1.0 million for the year ended December 31, 2015 and €0.9 million for the year ended December 31, 2014.

General and administrative expenses were €6.3 million for the year ended December 31, 2014, an increase of €3.9 million, or 160%, compared to €2.4 million for the year ended December 31, 2013. Our overhead expenses are allocated to general and administrative and research and development functions based on the proportion of general and administrative to research and development employees. This increase is primarily due to an increase in professional fees relating to our initial public offering, or IPO, completed in February 2015, and personnel costs of €1.7 million for additional administrative personnel in support of our IPO and to respond to the increasing requirements of operating as a publicly traded company. General and administrative expenses included non-cash share-based payment of €0.9 million for the year ended December 31, 2014 and €0.1 million for the year ended December 31, 2013.

Finance Income and Finance Expenses

Finance income increased by €9.1 million to €11.0 million for the year ended December 31, 2015 compared to €1.9 million for the year ended December 31, 2014. Finance expenses increased by €2.6 million to €2.8 million for the year ended December 31, 2015 compared to €0.2 million for the year ended December 31, 2014. On a net basis, net finance income was €8.3 million for the year ended December 31, 2015, a net increase of €6.7 million compared to net finance income of €1.6 million for the year ended December 31, 2014. The significant increase in net finance income was due to positive exchange rate fluctuations, primarily between the U.S. dollars and Euro. We maintained the funds from our series D financing in November 2014 and IPO in February 2015 in U.S. dollars for a portion of the first quarter of 2015, generating a significant exchange rate gain. At the end of March 2015, we converted approximately $90 million to Euros and British Pounds, thereby realizing a significant exchange rate gain and reducing our exposure to exchange rate fluctuations, as these cash positions more closely reflect the currencies in which we expect to incur the majority of our future expenses. We 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.

Finance income increased by €1.7 million to €1.9 million for the year ended December 31, 2014 compared to €0.2 million for the year ended December 31, 2013. Finance expenses decreased by €0.5 million to €0.2 million compared to €0.7 million for the year ended December 31, 2013. On a net basis, net finance income was €1.6 million for the year ended December 31, 2014, a net increase of €2.2 million compared to net finance expenses of €0.6 million for the year ended December 31, 2013. The increase in net financial income was due to positive exchange rate fluctuations, primarily between the USD and EUR. In particular, the cash from the series D financing in November 2014 which was maintained in USD generated positive exchange rate gains in 2014.

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

Tax on Profit / (Loss) for the Year

Tax on loss for the year was a tax benefit of €0.7 million for the year ended December 31, 2015, which was in line with the tax benefit for the year ended December 31, 2014. 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, 2015, the jointly taxed Danish entities had a tax loss, and accordingly, were entitled to a tax refund of approximately €0.8 million. The tax on loss for the year ended December 31, 2015 further comprised tax provisions of €0.2 million related to our subsidiary in Germany and a tax credit of €0.1 million related to our subsidiary in the United States.

Tax for the year was a tax benefit of €0.7 million for the year ended December 31, 2014 compared to a tax expense of €0.6 million for the year ended December 31, 2013. For the year ended December 31, 2014, the jointly taxed Danish entities had a tax loss, and accordingly were entitled to a tax refund of approximately €0.8 million. The tax on loss for the year ended December 31, 2014 further comprised tax provisions of €0.1 million related to our subsidiary in Germany and €32,895 related to our subsidiary in the United States.

At December 31, 2015, 2014 and 2013, we had net deferred tax assets of €14.1 million, €7.0 million and €6.8 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 partly offset by a decrease in the tax value of deferred income. The deferred tax asset can be carried forward without timing limitations. For tax losses carried forward, certain limitations exist for amounts to be utilized each year.

Quantitative and Qualitative Disclosures about Market Risk

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

Foreign Currency Risk

We are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the U.S. dollar, the British Pound and the Danish Krone. Our functional currency is the euro, but we have received payments in U.S. dollars under our collaboration with Genentech and our prior collaboration with United Therapeutics. Further, the proceeds from our Series D financing in November 2014 and our IPO in February 2015 were in U.S. dollars. We seek to limit our to exchange rate risks by maintaining cash positions in the currencies in which we expect to incur the majority of our future expenses and we make payments from those reserves. We converted a portion of the proceeds from our IPO in U.S. dollars to our functional currency, the Euro, in March 2015, reducing the amount held in U.S. dollars, to better reflect the expected future cash burn. As required under IFRS, we perform an analysis and report on our foreign currency exposure on an annual basis. At December 31, 2015, the carrying amount of our foreign currency denominated monetary assets and liabilities was €71.0 million, and we held $73.8 million denominated in U.S. dollars, primarily related to the proceeds from the IPO completed in February 2015.

A sensitivity analysis of our exposure to USD based on outstanding foreign currency denominated monetary items as of December 31, 2015 shows that a strengthening of USD against EUR by 10% would increase net profit or loss and equity by €6.7 million. A 10% weakening of USD against EUR would decrease net profit or loss and equity by a similar amount.

A sensitivity analysis of our exposure to USD based on outstanding foreign currency denominated monetary items as of December 31, 2014 shows that a strengthening of USD against EUR by 10% would increase net profit or loss and equity by €4.7 million. A 10% weakening of USD against EUR would decrease net profit or loss and equity by a similar amount.

A sensitivity analysis of our exposure to USD based on outstanding foreign currency denominated monetary items as of December 31, 2013 shows that a strengthening of USD against EUR by 10% would increase net profit or loss and equity by €1.6 million. A 10% weakening of USD against EUR would decrease profit or loss and equity by a similar amount.

Interest Rate Risk

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

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

Credit Risk

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

Liquidity Risk

We manage our liquidity risk by maintaining adequate cash reserves at banking facilities, and by continuously monitoring our cash forecasts, our actual cash flows, and by matching the maturity profiles of financial assets and liabilities. Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2015 are sufficient to meet our projected cash requirements for at least the 12 months from the date of this annual report.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with IFRS as issued by the IASB. A description of our accounting policies is provided in the Accounting Policies section of the audited consolidated financial statements as of and for the years ended December 31, 2015, 2014 and 2013 included elsewhere in this annual report. In the application of our accounting policies, we are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. In some instances, we could have reasonably used different accounting estimates, and in other instances changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ significantly from the estimates we have made. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial conditions, results of operations and cash flows will be affected.

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

Critical Accounting Policies

We are required to make critical judgments when applying certain of our accounting policies. The following critical judgments have the most significant effect on amounts recognized in our consolidated financial statements.

Revenue Recognition

International Accounting Standard, IAS 18, “Revenues” prescribes the criteria to be fulfilled for revenue recognition. Evaluating the criteria for revenue recognition with respect to our research and development and commercialization agreements requires management’s judgment to ensure that all criteria have been fulfilled prior to recognizing any amount of revenue.

We generate revenue from our collaboration partners for the research and development of certain products which utilize our TransCon technology. Payments between collaboration partners are accounted for and presented in the results of operations after considering the specific nature of the payment and the underlying activities to which the payments relate. Collaboration agreements which contain multiple activities are only separated into individual units of accounting if they constitute a separate earnings process. If multiple activities or rights are not separable, they are combined into a single unit of accounting.

Under our collaboration agreements, we have licensed certain rights to our TransCon technology in exchange for up-front payments and potential future milestone payments tied to development and regulatory milestones, plus sales-related milestone payments and tiered royalties. Furthermore, we perform certain development activities according to agreed development plans for which we receive separate remuneration based on an agreed full-time-equivalent rate and reimbursement of external costs.

For each license and collaboration agreement, we determined that the rights transferred to our collaboration partners did not have standalone value as they were closely related to the agreed research and development activities and such rights were not sold separately by us or any other party, nor could any party receive full benefit for the delivered rights without the fulfillment of other ongoing obligations by us under the license and collaboration agreements. As a result, proceeds from up-front payments were deferred and recognized as revenue over the expected life of the joint development period. Although the collaboration agreements include payments for certain development and sales milestones, we did not recognize any such revenue during the periods presented as the criteria for recognition had not yet been met.

Cost reimbursements between the parties are recognized as incurred and included in research and development expenses.

Share-Based Payment

IFRS 2, "Share-Based Payment" requires an entity to reflect in its profit or loss and financial position the effects of share-based payment transactions, including expenses associated with transactions in which share options are granted to employees. We have granted warrants to our employees, consultants and board members under three different warrant programs, which are classified as equity-settled share-based payment arrangements under IFRS 2.

We recognize compensation costs related to these warrants based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. We estimate the grant date fair value, and the resulting share-based payment expense, using the Black-Scholes option-pricing model. The grant date fair value of the share-based awards is generally recognized on an accelerated basis over the requisite service period, i.e. each tranche of a warrant grant is treated separately for expense recognition purposes. Accordingly, each warrant grant is treated in up to 48 tranches, which are each recognized over the expected useful life of that particular tranche. Because our company's warrants vest on a monthly basis over periods up to 48 months, a higher percentage of total expense is recognized in the initial years after the grant date. Share-based payment expense was €1.7 million, €1.3 million and €0.7 million for the years ended December 31, 2015, 2014 and 2013, respectively.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of share-based awards. These assumptions include:

- *Expected Lifetime*—The expected lifetime of each individual warrant tranche represents the period that share-based awards are expected to be outstanding. The warrants may be exercised during two exercise periods that run 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 one specific grant in 2014, warrants may be exercised in four annual exercise periods that run 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 the outstanding warrants, which can be exercised until 21 days following the publication of our interim report (nine-month report) in 2023, we estimated the expected lifetime based on the weighted average of the time from grant date to date the warrants become exercisable and from grant date to expiry of the warrants, also considering the periods during which the warrants may be exercised.

- *Expected Volatility*—While we were a privately held company until February 2015, without any trading history for our ordinary shares, the expected volatility was estimated based on the average volatility for comparable publicly traded biopharmaceutical companies measured over a period equal to the expected lifetimes of the individual warrant tranches. When selecting comparable publicly traded biopharmaceutical companies on which we based our expected share price volatility, we selected companies with comparable characteristics to us, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to measure volatility over the expected lifetime of the share-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own share price becomes available.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the Danish government bond effective interest rate in effect at the time of grant with the same lifetime as the warrants.
- *Expected Dividend*—We have never paid dividends on our ordinary shares and have no plans to pay dividends on our ordinary shares or ADSs. Therefore, we provided for no payment of dividends in the Black-Scholes option pricing model.

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures, and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior, and other factors. To date, consistent with our expectations, we have experienced minimal forfeitures. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment, and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to share-based compensation in future periods.

Prior to November 2014, the exercise price at which our warrants could be exercised into our ordinary shares was set on each grant date at the value per share established for preference shares for the corresponding most recent round of equity financing. In connection with preparation for our initial public offering, our board of directors performed a valuation of our ordinary shares on a retrospective basis. Given the absence of a public trading market for our ordinary shares, the board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our ordinary shares in prior periods, including the relevant stage of development; progress of our research and development efforts; the rights, preferences and privileges of our preference shares relative to those of our ordinary shares; equity market conditions affecting comparable public companies; and the lack of marketability of our ordinary shares. Additionally, the board considered retrospective valuations of our ordinary shares prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. After considering all these factors, the board determined fair values of our ordinary shares at grant dates, which, at each date, were less than the exercise prices at which the warrants we granted could be exercised, as the exercise prices had been set at the value per share for preference shares.

In determining the fair value for our ordinary shares for periods up to December 31, 2012, we used the Option-Pricing Method, or OPM. For purposes of this method, we estimated the enterprise value based on the price of our most recent preference shares financing and consideration of incremental cash flows anticipated from milestone payments from our collaboration partners added after such financing. For periods subsequent to December 31, 2012, as there was less uncertainty regarding a potential exit event, we applied the hybrid method. Under the hybrid method, we estimated per-share values of our ordinary shares under different scenarios, using the Probability-Weighted Expected Return Method, or PWERM, for two of our exit scenarios, going public in twelve

months and in eighteen months, and the OPM for the remaining scenario of continuing to operate as a private company. For purposes of PWERM, we applied the market approach to determine the enterprise value. The market approach estimates the fair value of a company through estimation of a future value to be realized in a future initial public offering based on recent comparable biopharmaceutical companies' initial public offerings. Such value is discounted using an appropriate risk-adjusted discount factor based primarily on benchmark venture capital studies of discount rates for other companies in similar stages of development.

Under all methods, we allocated the enterprise value to our preference and ordinary shares and warrants based on rights and entitlements of these instruments. We then applied a discount for lack of marketability of our ordinary shares as our securities are not currently freely transferable, commensurate with the estimated timing and prospects of liquidity, and applied estimated probabilities of each contemplated scenario to determine the aggregate per-share value of our ordinary shares.

For valuations after the completion of our initial public offering, our board of directors determine the fair value of our ordinary shares based on the closing price of the ADSs as reported on the date of grant.

The intrinsic value of all outstanding warrants as of December 31, 2015 was €15.9 million based on the market price of our ADSs of $18.32.

Internally Generated Intangible Assets

IAS 38, "Intangible Assets" prescribes that intangible assets arising from development projects must be recognized in the consolidated statement 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 our senior management has the intent to produce and market the product or use it internally.

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

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

Joint Arrangements / Collaboration Agreements

Collaboration agreements within the biopharmaceutical industry are often structured so that each party contributes its respective skills in the various phases of a development project. No joint control exists for such collaborations and the parties do not have any financial obligations on behalf of each other. Our current collaboration agreements are not considered to be joint arrangements as defined in IFRS 11, "Joint Arrangements."

Key Sources of Estimation Uncertainty

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

Impairment of Goodwill

As required under IFRS, we perform an impairment test of goodwill on an annual basis, or more frequently to the extent indicators of impairment exist. For the years ended December 31, 2015, 2014 and 2013, the recoverable amount of goodwill has been determined based on fair value less cost to sell. For the year ended December 31, 2015, we determined the fair value of goodwill based on the market price of our ADSs and the total

outstanding number of shares. For the years ended December 31, 2014 and 2013, we determined the fair value of goodwill after taking into account the results of a third party valuation as of a corresponding consolidated statement of financial position date. The valuation methodologies we applied were based on a combination of a market approach, an option pricing method and a probability weighted expected return method. No indicators of impairment were identified as of December 31, 2015.

The market approach used before our IPO was based on market multiples of comparable publicly traded companies in the same industry or similar lines of business. The multiples and values were then applied to our corresponding financial metrics, as well as used for input to the option pricing method. When calculating the fair value using the option pricing method we used a market-based back solve approach to determine the enterprise value as of May 31, 2011, the date of our last round of financing, and then added the incremental value we derive from the cash flows we anticipate from our collaboration partners.

Under the probability weighted expected return method, the values of the various equity securities were estimated based upon an analysis of future values, assuming various future outcomes. Share value is based upon the probability-weighted present value of expected future investment returns, considering each of the possible future outcomes available, as well as the rights of each share class.

We weighted the values for each of the approaches based on the quality of the information specific to each valuation approach and expected exit outcomes.

Recognition of Accruals for Manufacturing and Clinical Trial Activities

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

Useful Lives of Property, Plant and Equipment and Finite-Lived Intangible Assets

We review the estimated useful lives of property, plant and equipment and finite-lived intangible assets at the end of each reporting period.

B. Liquidity and Capital Resources

As of December 31, 2015, we had cash and cash equivalents totaling €119.6 million. We have funded our operations primarily through issuance of our preference shares, ordinary shares and convertible debt securities and payments to us under our collaboration agreements. Our expenditures are primarily related to research and development activities and general and administrative activities to support research and development. We do not have any debt to third parties.

On February 2, 2015, we announced the closing of our initial public offering, with net proceeds of $111.5 million (or approximately €101.4 million at such date) after deducting underwriting discounts, commissions and offering expenses. Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2015 will be sufficient to meet our projected cash requirements for at least 12 months from the date of this annual report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including, but not limited to:

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

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

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

Since our inception, as of December 31, 2015, we have funded our operations through the sale of €186.6 million of our preference shares, ordinary shares and convertible debt securities, including our IPO and exercise of warrants, and we have received aggregate gross proceeds of approximately €73.3 million from collaboration partners for up-front technology licensing fees, assignment of certain intellectual property rights and for services rendered under those agreements.

The following table summarizes our cash flows for the years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,		
	2015	2014	2013
	(EUR'000)	(EUR'000)	(EUR'000)
Cash flows from/(used in) operating activities	(43,466)	(18,403)	6,310
Cash flows used in investing activities	(1,039)	(405)	(1,195)
Cash flows from/(used in) financing activities	105,742	47,907	(220)
Net increase in cash and cash equivalents	**61,237**	**29,099**	**4,895**

Cash flows from/(used in) Operating Activities

Cash flows used in operating activities for the year ended December 31, 2015 was €43.5 million compared to €18.4 million for the year ended December 31, 2014. The net loss for the year ended December 31, 2015 was €32.9 million, which was partially offset by non-cash charges of €0.6 million for depreciation and €1.7 million for share-based payment. Further, net finance income, primarily comprising exchange rate adjustments of €8.2 million and net tax income of €0.7 million, were reversed. The net change in working capital of €4.6 million primarily comprised a €4.8 million decrease in deferred income and a net increase in deposits, prepayments and receivables of €3.2 million, partly offset by an increase in trade payables and other payables of €3.4 million. We received income taxes of €0.7 million for the year ended December 31, 2015.

Cash flows used in operating activities for the year ended December 31, 2014 was €18.4 million compared to cash inflow of €6.3 million for the year ended December 31, 2013. The net loss for the year ended December 31, 2014 was €9.7 million, which was partially offset by non-cash charges of €0.5 million for depreciation and €1.3 million for share-based payment. Further, net finance income, primarily comprising exchange rate adjustments of €1.6 million, and net tax income of €0.7 million, were reversed. The net change in working capital of €7.4 million primarily comprised a €9.6 million decrease in deferred income, partly offset by an increase in trade payables and other payables of €2.6 million and a net increase in deposits, prepayments and receivables of €0.4 million. We paid income taxes of €0.8 million for the year ended December 31, 2014.

Cash flows from operating activities for the year ended December 31, 2013 were €6.3 million compared to cash flows used in operating activities of €0.7 million for the year ended December 31, 2012. The net profit for the year ended December 31, 2013 was €4.1 million, which was adjusted for non-cash charges of €0.4 million for depreciation and €0.7 million for share-based payment. Further, net finance charges, primarily comprising exchange rate adjustments of €0.6 million, and tax charges of €0.6 million, were reversed. The net change in working capital of €0.5 million primarily comprised a reduction in receivables, related to up-front payments and payments for services rendered from our collaboration partners of €4.0 million that was partially offset by €3.6 million from the recognition of deferred income.

Cash Flows used in Investing Activities

Cash flows used in investing activities for the year ended December 31, 2015 of €1.0 million was related to the acquisition of property, plant and equipment, primarily for use in the laboratories of our German facility and new office space in Denmark and in the United States.

Cash flows used in investing activities for the years ended December 31, 2014 and 2013 of €0.4 million and €1.2 million, respectively, were solely related to the acquisition of property, plant and equipment, primarily for use in the laboratories of our German facility.

Cash Flows from / (used in) Financing Activities

Cash flows from financing activities for the year ended December 31, 2015 of €105.7 million were related to our IPO completed in February 2015 in which we raised net proceeds of €101.4 million, and warrant exercises in May, June, August and September 2015 in which we received €4.3 million.

Cash flows from financing activities for the year ended December 31, 2014 of €47.9 million were solely related to the series D financing round in November 2014, raising net proceeds to the company of €47.9 million.

Cash flows used in financing activities for the year ended December 31, 2013 of €0.2 million were solely related to installments on long-term financial liabilities. In 2010, we entered into a lease arrangement for laboratory equipment and in 2013, paid the last installment of the lease. We ultimately acquired the equipment at the end of the lease term. We had no further payment obligations on any of our laboratory equipment as of December 31, 2013.

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

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

D. Trend Information

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

E. Off-Balance Sheet Arrangements

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

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2015:

	Payments Due by Period				
Contractual Obligations:	**Less Than 1 Year**	**1 to 3 Years**	**3 to 5 Years**	**More Than 5 Years**	**Total**
			(EUR'000)		
Operating Lease Obligations(1)	971	1,103	827	767	3,668
Purchase Obligations(2)	2,400	—	—	—	2,400
Total contractual obligations	3,371	1,103	827	767	6,068

(1) Operating Lease Obligations primarily comprise leased offices in Denmark and the United States, and leased offices and laboratories in Germany.
(2) Purchase Obligations comprise committed minimum purchases under agreements with suppliers of goods.

G. Safe harbor

See "Forward Looking Statements".

Item 6 *Directors, Senior Management and Employees*

A. Directors and Senior Management

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

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

Board of Directors

The following table sets forth information with respect to each of our board members and their respective ages as of December 31, 2015. 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, classified into two classes. 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 5, DK-2900 Hellerup, Denmark.

Name of Board Member	Age	Position(s)	Term Expires
Michael Wolff Jensen, L.L.M.	44	Chairman and Senior Vice President, General Counsel	2017
Albert Cha, M.D., Ph.D.	43	Board Member	2016
James I. Healy, M.D., Ph.D.	50	Board Member	2017
Jan Møller Mikkelsen	56	President, Chief Executive Officer, Board Member and Executive Director	2017
Martin Olin	46	Board Member	2017
Jonathan T. Silverstein, J.D.	48	Board Member	2016
Rafaèle Tordjman, M.D., Ph.D.	46	Board Member	2017

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

Albert Cha, M.D., Ph.D. has served as a member of our board of directors since November 2014. In 2000, Dr. Cha joined Vivo Capital, a healthcare investment firm, where he has served in various positions, most recently as a managing partner. Dr. Cha currently serves as a member of the board of directors of several privately held biotechnology and medical device companies. Dr. Cha serves as a member of the board of directors at the following publicly traded companies: AirXpanders Inc., Aclaris Therapeutics, Inc., Carbylan Therapeutics, Inc., and ProNAi Therapeutics, Inc. From June 2002 through February 2009, Dr. Cha served as a member of the board of directors at BioForm Medical, Inc., a publicly traded medical aesthetics company. Dr. Cha holds a B.S. and an M.S. from Stanford University and an M.D. and a Ph.D. from the University of California at Los Angeles.

James I. Healy, M.D., Ph.D. has served as a member of our board of directors since November 2014. Dr. Healy has been a General Partner of Sofinnova Ventures, a 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 Amarin Corporation plc, Auris Medical Holding AG, Hyperion Therapeutics, Inc., Coherus BioSciences, Inc. and several private companies. Previously, he served as a board member of InterMune, Inc., Anthera Pharmaceuticals, Inc., Durata Therapeutics, Inc., CoTherix, Inc., Movetis NV, KaloBios Pharmaceuticals, Inc. 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.

Martin Olin has served as a member of our board of directors since June 2014. Since March 2012, Mr. Olin has served as the Chief Financial Officer of Symphogen A/S, a privately held biotechnology company, and, since February 2016, Mr. Olin has also served as Symphogen's Deputy Chief Executive Officer. Prior to his positions with Symphogen, Mr. Olin served as an Investment Director of SLS Invest ApS, a venture capital firm specializing in life sciences companies from January 2009 to March 2012. Prior to SLS Invest, Mr. Olin served as a Senior Partner of Scandinavian Life Science Venture, a life-science focused venture capital company later acquired by SLS Invest. Mr. Olin holds a B.Sc. in Business and Administration from Vestsjaellands Business School, an M.Sc. in Auditing and Business Administration from Copenhagen Business School and an Executive M.B.A. from Scandinavian International Management Institute.

Jonathan T. Silverstein, J.D. has served as a member of our board of directors since November 2014. Mr. Silverstein has been a member of OrbiMed Advisors LLC, an asset management firm solely focused in healthcare, since 1999. Prior to OrbiMed, Mr. Silverstein was a director of life sciences in the investment banking department at Sumitomo Bank, a financial services company. Since August 2012, Mr. Silverstein has served as a director of

Intercept Pharmaceuticals, Inc., a biopharmaceutical company; since September 2009, Mr. Silverstein has served as a director of Roka BioScience, Inc., a molecular diagnostics company; and, since July 2008, Mr. Silverstein has served as a director of Glaukos Corporation, an ophthalmic medical device company. In addition, Mr. Silverstein currently serves as a member of the board of directors of a number of private companies. From 2010 to July 2014, Mr. Silverstein was a director of Relypsa, Inc. From 2008 until 2011, Mr. Silverstein was a director of NxStage Medical, Inc. From 2006 until 2008, Mr. Silverstein was a director of Insulet, Inc. From 2004 until 2007, Mr. Silverstein was a director of Avanir Pharmaceuticals, Inc. Mr. Silverstein has a B.A. in economics from Denison University and a J.D. and M.B.A. from the University of San Diego.

Rafaèle Tordjman, M.D., Ph.D. has served as a member of our board of directors since December 2007. Dr. Tordjman joined the French venture capital firm Sofinnova Partners in 2001 and is a Managing Partner specializing in life sciences investments. Dr. Tordjman has also served on the boards of directors at several life sciences companies including DBV Technologies SA, a French publicly traded company specializing in allergy therapies, and Flexion Therapeutics, Inc., a publicly traded company specializing in clinical-stage pharmaceuticals. Previously, Dr. Tordjman was a research scientist at the Institut National de la Santé et de la Recherche Médicale (INSERM) in Cochin Hospital, Paris, France. Dr. Tordjman has also practiced as a medical doctor, specializing in clinical hematology and internal medicine. Dr. Tordjman received an M.D. and completed a fellowship in hematology and internal medicine at the Paris University Hospitals. She received a Ph.D. in hematopoiesis and angiogenesis from and completed a post-doctoral fellowship in immunology, at the University of Paris VII.

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, 2015. In addition to serving as members of our senior management, Mr. Mikkelsen currently serves as the sole member of our executive board. The business address of these members of our senior management is our registered office address at Tuborg Boulevard 5, DK-2900 Hellerup, Denmark.

Name	Age	Position(s)
Jan Møller Mikkelsen	56	President, Chief Executive Officer, Board Member and Executive Director
Martin Auster, M.D.	40	Senior Vice President, Chief Business Officer
Flemming Steen Jensen	54	Senior Vice President, Product Supply
Michael Wolff Jensen, L.L.M.	44	Chairman and Senior Vice President, General Counsel
Jonathan Leff, M.D.	58	Senior Vice President, Chief Medical Officer
Grethe Rasmussen, Ph.D.	53	Senior Vice President, Product Development
Peter Rasmussen	47	Vice President, Finance and Principal Financial and Accounting Officer
Dr. Harald Rau	45	Senior Vice President, Chief Scientific Officer
Lotte Sønderbjerg	54	Senior Vice President, Chief Administrative Officer
Kennett Sprogøe, Ph.D.	37	Senior Vice President, Product Innovation

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

Jan Møller Mikkelsen co-founded Ascendis Pharma and has served as our President and Chief Executive Officer and as a member of our board of directors since December 2007. From 2002 to 2006, Mr. Mikkelsen served as President and Chief Executive Officer of LifeCycle Pharma A/S, now known as Veloxis Pharmaceuticals A/S, a publicly traded biotechnology company. From 2000 to 2002, Mr. Mikkelsen served as Co-President and subsequently as President of the Pharmaceutical Division of Maxygen, Inc., a protein pharmaceuticals business. Mr. Mikkelsen co-founded ProFound Pharma A/S, a biopharmaceutical company that was later acquired by Maxygen, Inc., and he served as Co-Chief Executive Officer from 1999 to 2000. Prior to founding ProFound, Mr. Mikkelsen held various positions at Novo Nordisk A/S, a global healthcare company, and served as its Vice President of protein discovery from 1991 to 1999. Mr. Mikkelsen currently serves as a member of the advisory board of Inspirion Delivery Technologies, a specialty pharmaceutical company. Mr. Mikkelsen is Cand. Scient. in Biochemistry from the University of Odense.

Martin Auster, M.D. joined our company in May 2014 as our Senior Vice President, Chief Business Officer. Prior to Ascendis Pharma, Dr. Auster served as Vice President, Business Development at United Therapeutics Corporation, a publicly traded biotechnology company, from March 2009 to May 2014. Prior to United Therapeutics, Dr. Auster held several positions in the investment banking industry including as a Biotechnology Analyst at Morgan Stanley, as a Senior Biotechnology Analyst at Wachovia Securities, and as a Senior Analyst at GLG Partners, Inc. Dr. Auster received a B.A. from the University of Michigan and an M.D. from the University of Texas Medical Branch.

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

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

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

Grethe Rasmussen, Ph.D. has served as our Senior Vice President, Product Development since April 2008. From 2000 to 2007, Dr. Rasmussen served as Vice President for Protein Science at Maxygen, Inc. and from 2007 she served as Managing Director for the Danish subsidiary of Maxygen. Prior to joining Maxygen from 1989 to 2000, Dr. Rasmussen held various positions at Novo Nordisk A/S, a global healthcare company, where she contributed to research and development of protein chemistry. Dr. Rasmussen received a Ph.D. in Biochemistry from the Danish Technical University.

Peter Rasmussen joined our company in March 2014 as Vice President, Finance and Principal Accounting Officer and has served as our Principal Financial Officer since February 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.

Dr. Harald Rau has served as our Senior Vice President, Chief Scientific Officer, managing the research group at Ascendis Pharma since December 2007. Prior to Ascendis Pharma, Dr. Rau served as the Chief Scientific Officer of Complex Biosystems GmbH, a biotechnology company Dr. Rau co-founded in 2002, which was acquired by Ascendis Pharma in December 2007. Prior to co-founding Complex Biosystems, Dr. Rau worked with Graffinity Pharmaceuticals AG, a biotechnology company, from 1998 to 2002, and served as its Director of Chemistry from 2000 to 2002. Dr. Rau obtained his doctorate from the University of Freiburg.

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

Kennett Sprogøe, Ph.D. has held positions of increasing responsibility at Ascendis Pharma since December 2007, including serving as our Senior Vice President, Product Innovation since January 2016, our Vice President, Product Innovation from June 2014 to January 2016 and our Director, Portfolio Development from November 2012 to 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.

B. Compensation

Compensation of Members of Our Board of Directors and Senior Management

During 2015, Dr. Cha received board fees in the amount of €23,520 for his membership on our board and €2,940 for his tenure on the remuneration committee, Dr. Healy received €23,520 for his membership on our board and €5,063 for his tenure on the nominating and corporate governance committee and the audit committee, Mr. Silverstein received €23,520 for his membership on our board and €5,553 for his tenure on the nominating and corporate governance committee and the audit committee, Dr. Tordjman received €23,520 for her membership on our board and €8,820 for her tenure on the remuneration committee and nominating and corporate governance committee, and Mr. Olin received €33,644 for his membership on our board and €15,556 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.

In addition, our former members of the board received fees for their services until they resigned from the board. During 2015, Mr. de Graaf received €20,907 for his membership on our board and €5,227 for his tenure on the audit committee, and Mr. Mayer received €13,067 for his membership on our board and €3,267 for his tenure on the audit committee. On December 18, 2015, Dr. Cha, Dr. Healy, Mr. Silverstein and Dr. Tordjman were each granted 35,000 warrants, and Mr. Olin was granted 15,408 warrants, in each case with an exercise price per share of $16.99 (€15.6750) and an expiration date on December 18, 2025. The aggregate grant date fair value of the warrants granted to our board members in 2015 for their services as board members was €1,352,503.

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. In addition, 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 2015, consisting of Messrs. Mikkelsen, Michael Wolff Jensen, Peter Rasmussen, Soloway, Flemming Steen Jensen and Ms. Sønderbjerg and Drs. Auster, Sprogøe, Grethe Rasmussen and Rau, for the fiscal year ended December 31, 2015 was approximately €5.5 million. This amount consists of: (i) short-term employee benefits including salary and other in-kind benefits of approximately €2.8 million, (ii) bonuses of €1.4 million, (iii) share-based payments of approximately €1.3 million, and (iv) post-employment benefits of €1,200. Share-based payments reflect the 2015 expenses of warrants granted in or before 2015. During 2015, the board made the following warrant grants to members of our senior management who were employed by our company during 2015:

Name	Grant Date	Awards Granted	Award Exercise Price(s)	Award Expiration Date
Jan Møller Mikkelsen	December 18, 2015	220,000	$16.99 (€15.6750)	December 18, 2025
Thomas P. Soloway	-	-	-	-
Michael Wolff Jensen	December 18, 2015	50,000	$16.99 (€15.6750)	December 18, 2025
Harald Rau	-	-	-	-
Martin Auster	-	-	-	-
Lotte Sønderbjerg	December 18, 2015	80,000	$16.99 (€15.6750)	December 18, 2025
Grethe Rasmussen	December 18, 2015	100,000	$16.99 (€15.6750)	December 18, 2025
Flemming Steen Jensen	December 18, 2015	100,000	$16.99 (€15.6750)	December 18, 2025
Kennett Sprogøe	December 18, 2015	90,000	$16.99 (€15.6750)	December 18, 2025
Peter Rasmussen	December 18, 2015	10,000	$16.99 (€15.6750)	December 18, 2025

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, 2015 was €0.

Senior Management Agreements

We have entered into employment or service agreements with our senior management. The employment agreement with Mr. Mikkelsen contains a termination notice period of six months for a termination by Mr. Mikkelsen and 12 months' for a termination by us. It also provides that during the 12-month period following a change of control ("change in control period"), we may only terminate Mr. Mikkelsen's employment with 18 months' notice. In addition, if during the change in control period, the position and responsibilities of Mr. Mikkelsen are changed (excluding insignificant changes), Mr. Mikkelsen will be entitled to regard his employment as having been terminated by us with 12 months' notice.

The agreements with Messrs. Michael Wolff Jensen and Flemming Steen Jensen, Ms. Sønderbjerg and Dr. Grethe Rasmussen contain a termination notice period of three months for a termination by the employee and six months for a termination by us (except that in the case of Ms. Sønderbjerg and Dr. Grethe Rasmussen, the notice period may be no less than the notice required pursuant to the rules of the Danish Salaried Employees Act with the addition of two months). The agreement with Mr. Peter Rasmussen contains a termination notice period of one month for a termination by the employee and three months for a termination by us (except that the notice period may be no less than the notice required pursuant to the rules of the Danish Salaried Employees Act). The agreement with Dr. Rau contains a termination notice period of six months for a termination by the employee or by us (other than in the case of a termination for good cause which does not require notice). The agreement with Dr. Sprogøe contains a termination notice period of one month for a termination by the employee and six months for a termination by us. The employment agreement with Dr. Auster provides that in the event of nonrenewal of the employment agreement, a termination without cause by us or a termination for good reason by the employee, Dr. Auster will be entitled to six months' continued salary and benefits. The agreements with certain of our senior management contain post-termination non-competition covenants that generally may last for a period of 12 months post-termination and entitle the executives to their base salary, or portion thereof, during the period.

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 3,798,592 warrants in the period ending December 31, 2019; however, warrants cannot be issued to the extent that outstanding and non-exercised warrants issued under that authorization are equal to 20% or more of our Company's registered share capital.

The grant of warrants to any participant is at the discretion of our board of directors and based on the recommendation of our management. The board of directors may determine the terms and conditions of the warrants issued, including exercise periods, subscription price and adjustments caused by changes to our company's situation.

Subject to earlier vesting upon the occurrence of certain exit events, warrants granted under the program as in effect since December 18, 2015 generally vest 1/48th per month from the date of grant subject to continued service for employees, consultants and initial grants to board members and 1/24th per month from the date of grant subject to continued service for subsequent grants to board members. Warrants granted under the program as in effect between December 2012 and December 18, 2015 generally vest 1/48th per month from the date of grant subject to continued service (previously 1/36th per month for employees and 1/24th per month from the date of grant for board members). With respect to employees, in the event that a holder resigns due to our breach of employment terms or we terminate the employment relationship and the holder has not given us good reason to do so, the warrants will continue to vest post-termination in accordance with the same vesting schedule. Otherwise, warrants will cease vesting upon termination of service with respect to employees, board members and consultants.

Vested warrants may be exercised during certain exercise periods each year. For 1,054,958 outstanding warrants, there are two annual exercise periods that continue for 21 days from and including the day after the publication of (i) the annual report notification—or if such notification is not published—the annual report and (ii) our interim report (six-month report). For these warrants, the last exercise period is 21 days from and including the day after the publication of our interim report for the first half of 2023. For 538,037 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 1,022,908 outstanding warrants granted on December 18, 2015 and 178,500 outstanding warrants granted on March 15, 2016, there are four annual exercise periods; each exercise period begins two full trading days after the publication of the public release of our earnings data of a fiscal quarter and continues until the end of the second-to-last trading day in which quarter the relevant earnings release is published. The warrants granted in December 2015 and March 2016 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 31, 2016.

Name	Grant Date	Awards granted and outstanding	Awards granted and outstanding, but unvested as of May 31, 2016	Award Exercise Price(s)	Award Expiration Date
Jan Møller Mikkelsen	December 3, 2012	319,372	46,576	€ 7.9962	21 days following our interim report (six-month report) in 2023
	November 26, 2014	191,624	119,765	€ 6.4775	21 days following our interim report (nine-month report) in 2023
	December 18, 2015	220,000	197,084	€ 15.6750	December 18, 2025
Dr. Harald Rau	December 3, 2012	176,528	18,389	€ 7.9962	21 days following our interim report (six-month report) in 2023
	November 26, 2014	105,916	66,198	€ 6.4775	21 days following our interim report (nine-month report) in 2023
James I. Healy, M.D., Ph.D.	December 18, 2015	35,000	31,355	€ 15.6750	December 18, 2025
Rafaèle Tordjman, M.D., Ph.D.	December 18, 2015	35,000	31,355	€ 15.6750	December 18, 2025
Albert Cha, M.D., Ph.D.	December 18, 2015	35,000	31,355	€ 15.6750	December 18, 2025

Insurance and Indemnification

According to the Danish Companies Act, the general meeting is allowed to discharge our board members and members of our senior management from liability for any particular financial year based on a resolution relating to the financial statements. This discharge means that the general meeting will discharge such board members and members of our senior management from liability to our company; however, the general meeting cannot discharge any claims by individual shareholders or other third parties.

Additionally, we have entered into agreements with our board members and members of our senior management, pursuant to which, subject to limited exceptions, we have agreed to indemnify such board members and members of our senior management from civil liability, including (i) any damages or fines payable by them as a result of an act or failure to act in the exercise of their duties currently or previously performed by them; (ii) any reasonable costs of conducting a defense against a claim; and (iii) any reasonable costs of appearing in other legal proceedings in which such individuals are involved as current or former board members or members of our senior management.

There is a risk that such agreement will be deemed void under Danish law, either because the agreement is deemed contrary to the rules on discharge of liability in the Danish Companies Act, as set forth above, because the agreement is deemed contrary to sections 19 and 23 of the Danish Act on Damages, which contain mandatory provisions on recourse claims between an employee (including members of our senior management) and the company, or because the agreement is deemed contrary to the general provisions of the Danish Contracts Act.

In addition to such indemnification, we provide our board members and senior management with directors' and officers' liability insurance.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to board members and senior management or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

C. Board Practices

Board of Directors

Our board of directors is responsible for our overall and strategic management and must ensure proper organization of our business. In addition, our board is obligated to ensure that (i) bookkeeping and financial reporting procedures are satisfactory; (ii) adequate risk management and internal control procedures have been established; (iii) our board of directors receives ongoing information as necessary about our financial position; (iv) our executive board performs its duties properly and as directed by our board of directors; and (v) the financial resources of our company are adequate at all times, and that our company has sufficient liquidity to meet its current and future liabilities as they become due.

In performing its duties, our board of directors is required to act in the interests of our company (including our shareholders) and our associated business as a whole. Our board of directors may generally make any decisions in furtherance of our objectives that are not reserved for either the executive board or the shareholders either by virtue of the articles of association or by operation of Danish law. Typical shareholder decisions that our board of directors cannot resolve alone are: changes to the articles of association, elections of board members, elections of auditors, decisions to scrutinize our company's affairs, capital increases and decreases, payment of dividends, purchase of treasury shares, and decisions to merge, demerge or liquidate our company.

The general meeting of shareholders must elect no fewer than three and no more than 10 members to our board of directors. The board of directors is classified into two classes as nearly equal in number as possible with respect to the duration of the term in which they severally hold office. Such classes consist of one class of directors ("Class I") who were elected at the annual general meeting held in 2015 for a term expiring at the annual general meeting to be held 2017; and a second class of directors ("Class II") who were elected at the annual general meeting held in 2015 for a term expiring at the annual general meeting to be held in 2016. The shareholders shall increase or decrease the number of directors, in order to ensure that the two classes shall be as nearly equal in number as possible; provided, however, that no decrease shall have the effect of shortening the term of any other director. At each annual general meeting beginning in 2016, the successors of the class of directors whose term expires at that meeting shall be elected to hold office for a term expiring at the annual general meeting held in the second year following the year of their election.

Board members may be dismissed at any time at a general meeting of shareholders. A resolution by the general meeting of shareholders to appoint or dismiss board members requires a simple majority of the votes cast and there is no requirement for a specific quorum.

Under Danish corporate law, employees of companies that have employed at least 35 employees for the preceding three years are entitled to elect members of their board of directors corresponding to one-half of the members of their board of directors elected by the general meeting of shareholders. Board members elected by the employees are elected for terms of four years, and they hold the same rights and obligations as any board member elected by the shareholders. We do not currently have employee representatives on our board of directors.

Our board of directors elects its chairman. Our board of directors forms a quorum when more than half of the members of our board of directors are represented. Resolutions of our board of directors are passed by simple majority. Each board member is entitled to cast one vote. For a complete description of these board governance matters, you should refer to our articles of association, which are incorporated by reference as an exhibit to this annual report.

Our board of directors may also adopt resolutions without a meeting, provided that such resolutions are adopted in writing and submitted to all members of our board of directors and provided that no board member objects to adopting resolutions without conducting a meeting.

As a foreign private issuer, our board of directors is not required to hold regularly scheduled meetings at which only independent board members are present and we intend to comply with home country practices, which do not require executive sessions, in lieu of complying with NASDAQ Rule 5605(b)(2).

Mr. Mikkelsen and Mr. Jensen are members of our senior management and members of our board of directors and these individuals have employment agreements that provide for benefits upon termination of employment in certain circumstances. For information about such agreements, see "Item 6 B. Compensation—Senior Management Agreements."

Executive Board

Our executive board is in charge of the day-to-day management of our operations and is assisted in this respect by the other members of our senior management. The executive board must follow the guidelines and directions issued by the board of directors. Day-to-day management does not include decisions of an unusual nature or of major importance, having regard to the circumstance. Such decisions may only be made by the executive board if specifically authorized by the board of directors, unless it will cause considerable inconvenience to our company's activities to wait for authorization by the board of directors. If so, the board of directors must be notified of the decision as soon as possible.

In accordance with the exemption available to foreign private issuers under NASDAQ rules, we do not follow the requirements of the NASDAQ rules with regard to the process of nominating board members, and instead, follow Danish law and practice, in accordance with which our board of directors (or a committee thereof) is authorized to recommend to our shareholders director nominees for election. Under the Danish Companies Act, nominations for directors also may be made upon the request of any shareholder.

Director Independence

Our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise their ability to exercise independent judgment in carrying out the responsibilities of a director. As a result of this review, our board of directors determined that Albert Cha, M.D., Ph.D., James I. Healy, M.D., Ph.D., Martin Olin, Jonathan T. Silverstein, J.D. and Rafaèle Tordjman, M.D., Ph.D. 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 Martin Olin (Chairman), Jonathan T. Silverstein, J.D. and James I. Healy, M.D., Ph.D. Each member satisfies the independence requirements of the NASDAQ listing standards, and Martin Olin qualifies as an "audit committee financial expert," as defined in Item 16A of Form 20-F and as determined by our board of directors. Our audit committee oversees our accounting and financial reporting processes and the audits of our consolidated financial statements. Our Audit committee meets all of the relevant criteria for independence under NASDAQ rule 5615. 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). 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 Rafaèle Tordjman, M.D., Ph.D., Martin Olin and Albert Cha, M.D., Ph.D. 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), Rafaèle Tordjman, M.D., Ph.D. and Jonathan T. Silverstein, J.D. Each member satisfies the independence requirements of the NASDAQ listing standards. Our nominating and corporate governance committee assists the board of directors in selecting individuals qualified to become our board members and in determining the composition of the board of directors and its committees. Our nominating and corporate governance committee is responsible for, among other things:

- recommending to our board of directors, persons to be nominated for election or re-election to our board of directors at any meeting of the shareholders;
- overseeing our board of director's annual review of its own performance and the performance of its committees; and
- considering, preparing and recommending to our board of directors a set of corporate governance guidelines.

For information on current term of office and the period during which the members of our board of directors, executive board and our senior management have served in office see "—Directors and Senior Management."

D. Employees

As of December 31, 2015, we employed 78 full-time employees, 30 of whom hold a Ph.D., M.D., or equivalent degrees. Of these full-time employees, 67 were engaged in research and development and 11 were engaged in general and administrative activities, including business and corporate development. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our employee relations to be good.

E. Share Ownership

See "Item 7 A. Major Shareholders and Related Party Transactions – Major Shareholders." Our employees are eligible to own shares of the company through a warrant incentive plan. For information on the plan, see "Item 6 B. Compensation—Warrant Incentive Plan."

Item 7 *Major Shareholders and Related Party Transactions*

A. Major Shareholders

The following table sets forth information relating to the beneficial ownership of our shares as of March 31, 2016, 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 31, 2016 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 25,128,242 ordinary shares outstanding as of March 31, 2016. Ordinary shares that a person has the right to subscribe for within 60 days of March 31, 2016 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 31, 2016, 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 5, DK-2900 Hellerup, Denmark.

Name and Address of Beneficial Owner	Beneficial Ownership: Number of Outstanding Shares Beneficially Owned	Number of Warrants Exercisable Within 60 Days	Number of Shares Beneficially Owned	Percentage of Beneficial Ownership
5% and Greater Shareholders				
Sofinnova Capital V FCPR(1)	5,582,174	—	5,582,174	22.2%
Entities affiliated with FMR LLC(2)	2,310,741	—	2,310,741	9.2%
Gilde Healthcare II Sub-Holding B.V.(3)	1,859,136	—	1,859,136	7.4%
Sofinnova Venture Partners IX, L.P.(4)	1,703,199	—	1,703,199	6.8%
OrbiMed Private Investments V, L.P.(5)	1,703,199	—	1,703,199	6.8%
Entities affiliated with RA Capital Management, LLC(6)	1,671,447	—	1,671,447	6.7%
Zweite TechnoStart Ventures Fonds GmbH & Co. KG i.L.(7)	1,661,056	—	1,661,056	6.6%
Entities affiliated with Vivo Capital(8)	1,419,332	—	1,419,332	5.6%
Visium Balanced Master Fund, Ltd.(9)	1,370,000	—	1,370,000	5.5%
Board Members and Senior Management				
Jan Møller Mikkelsen(10)	638,740	367,571	1,006,311	3.9%
Dr. Harald Rau(11)	146,240	197,857	344,097	1.4%
Michael Wolff Jensen, L.L.M.(12)	—	84,881	84,881	*
Grethe Rasmussen, Ph.D.(13)	—	42,573	42,573	*
Lotte Sønderbjerg(14)	—	40,490	40,490	*
Martin Auster, M.D.(15)	—	72,370	72,370	*
Peter Rasmussen(16)	—	18,307	18,307	*
Jonathan Leff, M.D.(17)	—	5,000	5,000	*
Flemming Steen Jensen(18)	—	10,416	10,416	*
Kennett Sprogøe, Ph.D.(19)	—	24,940	24,940	*
Rafaèle Tordjman, M.D., Ph.D.(20)	5,582,174	3,645	5,585,819	22.2%
Martin Olin(21)	—	15,689	15,689	*
James I. Healy, M.D., Ph.D.(22)	1,703,199	3,645	1,706,844	6.8%
Jonathan T. Silverstein, J.D.(23)	—	3,645	3,645	*
Albert Cha, M.D., Ph.D.(24)	1,419,332	3,645	1,422,977	5.7%

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

(1) Consists of an aggregate of 5,582,174 ADSs held by Sofinnova Capital V FCPR. Sofinnova Partners SAS, a French corporation and the management company of Sofinnova Capital V FCPR, may be deemed to have sole voting and investment power, and the managing partners of Sofinnova Partners SAS, Denis Lucquin, Antoine Papiernik, Rafaèle Tordjman, M.D., Ph.D. and Monique Saulnier, may be deemed to have shared voting and investment power with respect to such shares. The address of Sofinnova Capital V FCPR is Sofinnova Partners, Immeuble le Centorial, 16-18 Rue du Quatre-Septembre, 75002 Paris, France.

(2) Consists of an aggregate of 2,310,741 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 Schedule 13G filed on February 12, 2016 by FMR LLC. Abigail P. Johnson is a Director, the Vice Chairman, the Chief Executive Officer and the President 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 ("FMR Co"), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. FMR LLC has its principal business office at 245 Summer Street, Boston, MA 02210.

(3) Consists of 1,859,136 ordinary shares held by Gilde Healthcare II Sub-Holding B.V. ("Gilde Healthcare"), as reported on Schedule 13G filed with the SEC on February 9, 2016 by Gilde Healthcare Holding B.V. ("Gilde Holding"). The manager of Gilde Healthcare is Gilde Healthcare II Management B.V. ("Gilde Management"), and Gilde Management is owned by Gilde Holding. Three managing partners, via their personal holding companies Manapouri B.V. (of which Edwin de Graaf is the owner and manager), Charlofix B.V. (of which Marc Olivier Perret is the owner and manager) and Martemanshurk B.V. (of which Pieter van der Meer is the owner and manager) each own interests in Gilde Holding and Stichting Administratiekantoor Gilde Healthcare Holding ("Stichting"), owns interests in Gilde Holding. Stichting is controlled by Manapouri B.V., Charlofix B.V. and Martemanshurk B.V. and issued depository receipts for shares in Gilde Holding to Manapouri B.V., Charlofix B.V., Martemanshurk B.V. and Franken Ventures B.V. (of which Arthur Franken is owner and manager). Each of Mr. de Graaf, Mr. Perret and Mr. van der Meer share voting and dispositive power of the shares, and disclaim beneficial ownership of the shares except to the extent of their respective pecuniary interest therein. The address of Gilde Healthcare II Sub-Holding B.V. is Newtonlaan 91, 3584 BP, Utrecht, The Netherlands.

(4) Consists of (i) 1,480,976 ordinary shares and (ii) 222,223 ADSs held by Sofinnova Venture Partners IX, L.P. ("SVP IX"). Sofinnova Management IX, L.L.C. ("SM IX"), the general partner of SVP IX, may be deemed to have sole power to vote and sole power to dispose of shares directly owned by SVP IX. Dr. Michael F. Powell, Dr. James I. Healy, and Dr. Anand Mehra, the managing members of SM IX, may be deemed to have shared voting and investment power over the shares directly owned by SVP IX. The address of SVP IX is c/o Sofinnova Ventures, Inc., 3000 Sand Hill Road, Bldg. 4, Suite 250, Menlo Park, California 94025.

(5) Consists of (i) 1,480,976 ordinary shares and (ii) 222,223 ADSs held by OrbiMed Private Investments V, LP ("OPI V"), as reported Amendment No. 1 to Schedule 13D filed with the SEC on November 20, 2015 by OrbiMed Advisors LLC ("Advisors"), OrbiMed Capital GP V LLC ("GP V"), and Samuel D. Isaly. GP V is the sole general partner of OPI V and as such may be deemed to indirectly beneficially own the shares held by OPI V. Advisors pursuant to its authority as the sole managing member of GP V may be deemed to indirectly beneficially own the shares held by OPI V. Mr. Isaly is the managing member of and owner of a controlling interest in Advisors. Advisors, GP V and Mr. Isaly may be deemed to have shared voting and investment power over the shares directly owned by OPI V. The address of OPI V is 601 Lexington Avenue, New York, NY 10022.

(6) Consists of 1,671,447 ADSs beneficially owned by RA Capital Management, LLC ("Capital"), as reported by Amendment No. 1 to Schedule 13G filed with the SEC on February 16, 2016 by RA Capital Healthcare Fund, L.P. (the "Fund"), Capital and Peter Kolchinsky. The Fund has the shared power to vote and the shared power to dispose of 1,458,758 ordinary shares. Capital is the general partner of the Fund and serves as investment advisor for a separately managed account (the "Account") and may be deemed a beneficial owner of the shares owned by the Fund and the Account. Mr. Kolchinsky is the manager of Capital and may be deemed a beneficial owner of the shares beneficially owned by Capital. Capital and Mr. Kolchinsky have the shared power to vote and the shared power to dispose of 1,671,447 ordinary shares. Capital and Mr. Kolchinsky disclaim beneficial ownership of the shares described herein. The address of the Fund, Capital and Mr. Kolchinsky is c/o RA Capital Management, LLC, 20 Park Plaza, Suite 1200, Boston, MA 02116.

(7) Consists of (i) 1,500,000 ordinary shares and (ii) 161,056 ADSs held by Zweite TechnoStart Ventures Fonds GmbH & Co. KG i.L. ("TechnoStart"). Mr. Mayer is the managing director of Zweite TechnoStart Ventures Verwaltungs GmbH, which is the general partner of TechnoStart, and as such Mr. Mayer exercises voting and dispositive control over the shares held by TechnoStart. The address of TechnoStart Ventures is Kernaeckerstr. 5, 71732 Tamm, Germany.

(8) Consists of (i) an aggregate of 1,389,059 ordinary shares and ADSs held by Vivo Ventures Fund VII, L.P. ("Vivo VII LP") and (ii) an aggregate of 30,273 ordinary shares and ADSs held by Vivo Ventures VII Affiliates Fund, L.P. ("Vivo VII Affiliates LP"). Vivo VII LLC is the general partner of each of Vivo VII LP and Vivo VII Affiliates LP and may be deemed to have shared power to vote and shared power to dispose of the shares directly owned by Vivo VII LP and Vivo VII Affiliates LP. The managing members of Vivo VII LLC are Drs. Albert Cha, Edgar Engleman, Frank Kung, Chen Yu and Mr. Shan Fu and may be deemed to have shared voting and dispositive power over the shares listed herein. The address for each of Vivo VII LP and Vivo VII Affiliates LP is c/o Vivo Capital, 575 High Street, Suite 201, Palo Alto, CA 94301.

(9) Consists of 1,370,000 ADSs held by Visium Balanced Master Fund, Ltd. ("VBMF"), an advisory client of Visium Asset Management, LP ("VAM"), as reported by Schedule 13G filed with the SEC on February 12, 2016 on behalf of VBMF, VAM, JG Asset, LLC ("JG Asset") and Jacob Gottlieb. VAM is the investment manager to VBMF and may be deemed to beneficially own the shares beneficially owned by VBMF. JG Asset is the General Partner to VAM and may be deemed to beneficially own the shares beneficially owned by VAM. Jacob Gottlieb as Managing Member of JG Asset may be deemed to beneficially own the shares beneficially owned by JG Asset. Each of VAM, JG Asset and Gottlieb disclaim beneficial ownership as to the Securities, except to the extent of his or its pecuniary interests therein. Each of VBMF, VAM, JG Asset and Jacob Gottlieb have shared voting power and shared dispositive power over the ADSs listed herein. The address of VBMF is c/o Visium Asset Management, LP, 888 Seventh Avenue, New York, NY 10019.

(10) Consists of (i) 638,740 ordinary shares held by Mr. Mikkelsen and (ii) 367,571 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Mr. Mikkelsen.

(11) Consists of (i) 146,240 ordinary shares held by Dr. Rau and (ii) 197,857 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Dr. Rau.

(12) Consists of 84,881 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Mr. Jensen.

(13) Consists of 42,573 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Dr. Rasmussen.

(14) Consists of 40,490 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Ms. Sønderbjerg.

(15) Consists of 72,370 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Dr. Auster.

(16) Consists of 18,307 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Mr. Rasmussen.

(17) Consists of 5,000 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Dr. Leff.

(18) Consists of 10,416 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Mr. Jensen.

(19) Consists of 24,940 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Dr. Sprogøe.

(20) Consists of (i) 3,645 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Dr. Tordjman and (ii) securities beneficially owned by Sofinnova Capital V FCPR as set forth in footnote 1. Dr. Tordjman disclaims beneficial ownership of the shares listed in footnote 1, except to the extent of her pecuniary interest therein.

(21) Consists of 15,689 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Mr. Olin.

(22) Consists of (i) 3,645 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Dr. Healy and (ii) securities beneficially owned by Sofinnova Venture Partners IX, L.P. as set forth in footnote 4. Dr. Healy disclaims beneficial ownership of the shares listed in footnote 4, except to the extent of his pecuniary interest therein.

(23) Consists of 3,645 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Mr. Silverstein.

(24) Consists of (i) 3,645 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 31, 2016 by Dr. Cha and (ii) securities beneficially owned by entities affiliated with Vivo Capital as set forth in footnote 8. Dr. Cha disclaims beneficial ownership of the shares listed in footnote 8, except to the extent of his pecuniary interest therein.

Record holders

As of March 31, 2016, assuming that all of our ordinary shares represented by ADSs are held by residents of the United States, approximately 91% of our outstanding ordinary shares were held in the United States by 7 holders of record and 9% of our outstanding ordinary shares were held outside of the United Stated by 4 holders of record. At such date, there were outstanding 19,182,316 ADSs, each representing one of our ordinary shares, and in the aggregate representing 76.3% of our outstanding ordinary shares. At such date there, was one holder 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, 2015 with any of our board members, our senior management and the owners of more than five percent of our share capital.

Sales and Subscriptions for Securities

2015 Initial Public Offering

In February 2015, we completed our initial public offering of ADSs at a price of $18.00 per share, raising $124.2 million before expenses and underwriting commissions. Certain of our existing institutional investors, including investors affiliated with certain of our board members, purchased an aggregate of 1,814,818 ADSs (or approximately $32.7 million) in the offering at the initial public offering price on the same terms as the ADSs sold to the public generally.

The following table sets forth the number of ADSs purchased by our related parties in our initial public offering.

Shareholder	Number of ADSs
Sofinnova Capital V FCPR(1)	185,186
Sofinnova Venture Partners IX, L.P.(2)	222,223
OrbiMed Private Investments V, L.P.	222,223
Entities affiliated with Vivo Capital(3)	185,186

(1) Rafaèle Tordjman, M.D., Ph.D., a member of our board of directors, is a managing partner of Sofinnova Partners.
(2) James I. Healy, M.D., Ph.D., a member of our board of directors, is a general partner of Sofinnova Ventures.
(3) Albert Cha, M.D., Ph.D., a member of our board of directors, is a managing partner of Vivo Capital.

Registration Rights Agreements

We entered into a registration rights agreement in November 2014 with certain holders of our ordinary shares, including Sofinnova Capital V FCPR, Sofinnova Venture Partners IX, L.P., OrbiMed Private Investments V, L.P. and entities affiliated with Vivo Capital. In December 2015, we entered into an amendment to this registration rights agreement, which provided that such registration rights will also apply to securities held by certain shareholders pursuant to our previously outstanding Preference C shares.

We entered into a registration rights agreement in December 2015 with certain entities affiliated with FMR LLC in connection with their purchase on December 14, 2015 of an aggregate of 1.0 million ADSs representing our ordinary shares. Pursuant to this agreement, we agreed to timely register such shares with the SEC subject to certain conditions.

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.

C. Interests of Experts and Counsel

Not applicable.

Item 8 ***Financial Information***

A. Consolidated Statements and Other Financial Information

See the financial statements beginning on page F-1.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Dividends

We do not at present plan to pay cash dividends on our ordinary shares. Under Danish law, the distribution of ordinary and extraordinary dividends requires the approval of a company's shareholders at a company's general meeting. The shareholders may not distribute dividends in excess of the recommendation from the board of directors and may only pay out dividends from our distributable reserves, which are defined as results from operations carried forward and reserves that are not bound by law after deduction of loss carried forward. It is possible under Danish law to pay out interim dividends. The decision to pay out interim dividends shall be accompanied by a balance sheet, and the board of directors determine whether it will be sufficient to use the balance sheet from the annual report or if an interim balance sheet for the period from the annual report period until the interim dividend payment shall be prepared. If interim dividends are paid out later than six months following the financial year for the latest annual report, an interim balance sheet showing that there are sufficient funds shall always be prepared.

B. Significant Changes

See Note 19 to the audited consolidated financial statements included elsewhere in this annual report.

Item 9 ***The Offer and Listing***

A. Offering 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. Our initial public offering was priced at $18.00 per ADS on January 27, 2015. The following table sets forth for the periods indicated the high and low sales prices per ordinary share as reported on The NASDAQ Global Select Market:

	Per ADS	
	High	Low
Year ended December 31,	**$**	**$**
2015 (from January 28, 2015 through December 31, 2015)	23.81	14.75
Quarter ended		
March 31, 2015 (from January 28, 2015 through March 31, 2015)	21.97	17.00
June 30, 2015	20.93	14.75
September 30, 2015	23.81	16.02
December 31, 2015	18.98	15.31
Month ended		
August 31, 2015	22.38	16.04
September 30, 2015	20.73	16.02
October 31, 2015	18.49	15.88
November 30, 2015	18.98	16.39
December 31, 2015	18.97	15.31
January 31, 2016	20.16	12.99
February 29, 2016	19.89	16.14
March 31, 2016	18.76	15.25
April 2016 (through April 14, 2016)	19.05	17.68

On April 14, 2016, the last reported sale price of the ADSs on The NASDAQ Global Select Market was $18.39 per share.

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

Our shareholders adopted the Articles of Association filed as Exhibit 3.1 to our report on Form 6-K originally filed with the SEC on February 2, 2015.

The information set forth in our registration statement on Form F-3 filed with the SEC on February 2, 2016, under the headings "Description of Share Capital – Articles of Association and Danish Corporate Law," and "Description of Share Capital – Comparison of Danish Corporate Law and our Articles of Association and Delaware Corporate Law" is incorporated herein by reference.

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. The summary is for general information only and does not purport to constitute exhaustive tax or legal advice. It is specifically noted that the summary does not address all possible tax consequences relating to an investment in the ADSs. The summary is based solely on the tax laws of Denmark in effect on the date of this annual report. Danish tax laws may be subject to change, possibly with retroactive effect.

The summary does not cover investors to whom special tax rules apply, and, therefore, may not be relevant, for example, to investors subject to the Danish Tax on Pension Yields Act (*i.e.*, pension savings), professional investors, certain institutional investors, insurance companies, pension companies, banks, stockbrokers and investors with tax liability on return on pension investments. The summary does not cover taxation of individuals and companies who carry on a business of purchasing and selling shares. The summary only sets out the tax position of the direct owners of the ADSs and further assumes that the direct investors are the beneficial owners of the ADSs and any dividends thereon. Sales are assumed to be sales to a third party.

Potential investors in the ADSs are advised to consult their tax advisors regarding the applicable tax consequences of acquiring, holding and disposing of the ADSs based on their particular circumstances.

Investors who may be affected by the tax laws of other jurisdictions should consult their tax advisors with respect to the tax consequences applicable to their particular circumstances as such consequences may differ significantly from those described herein.

Taxation of Danish Tax Resident Holders of the ADSs

When considering the taxation of Danish tax resident holders of the ADSs (companies and individuals), it is assumed that for tax purposes Danish tax resident holders of the ADSs should be treated as holders of unlisted shares in the company. It is currently not clear under the Danish tax legislation or case law how the listed ADSs are to be treated for tax purposes. For the purpose of the below comments, it is assumed that the ADSs listed in the U.S. should be treated as non-listed shares as the company's ordinary shares are not admitted to trading on a regulated market.

Sale of the ADSs (Individuals)

Gains from the sale of shares are taxed as share income at a rate of 27% on the first DKK 50,600 (for cohabiting spouses, a total of DKK 101,200) and at a rate of 42% on share income exceeding DKK 50,600 (for cohabiting spouses over DKK 101,200). 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 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 in order to prevent exemption through certain holding company structures just as other anti-avoidance rules may apply. These rules will not be described in further detail.

Capital gains from the sale of Taxable Portfolio Shares admitted to trading on a regulated market are taxable at a rate of 22% irrespective of ownership period. Losses on such shares are generally deductible. Gains and losses on Taxable Portfolio Shares admitted to trading on a regulated market are taxable according to the mark-to-market principle (in Danish "*lagerprincippet*").

According to the mark-to-market principle, each year's taxable gain or loss on Taxable Portfolio Shares is calculated as the difference between the market value of the shares at the beginning and end of the tax year. Thus, taxation will take place on an accrual basis even if no shares have been disposed of and no gains or losses have been realized.

If the Taxable Portfolio Shares are sold or otherwise disposed of before the end of the income year, the taxable income of that income year equals the difference between the value of the Taxable Portfolio Shares at the beginning of the income year and the value of the Taxable Portfolio Shares at realization. If the Taxable Portfolio Shares are acquired and realized in the same income year, the taxable income equals the difference between the acquisition sum and the realization sum. If the Taxable Portfolio Shares are acquired in the income year and not realized in the same income year, the taxable income equals the difference between the acquisition sum and the value of the shares at the end of the income years.

A change of status from Subsidiary Shares/Group Shares/Tax-Exempt Portfolio Shares to Taxable Portfolio Shares (or vice versa) is for tax purposes deemed to be a disposal of the shares and a reacquisition of the shares at market value at the time of change of status.

Special transitional rules apply with respect to the right to offset capital losses realized by the end of the 2009 income year against taxable gains on shares in the 2010 income year or later.

Dividends (Individuals)

Dividends paid to individuals who are tax residents of Denmark are taxed as share income, as described above. All share income must be included when calculating whether the amounts mentioned above are exceeded. Dividends paid to individuals are generally subject to 27% withholding tax.

Dividends (Companies)

Dividends paid on both Tax-Exempt and Taxable Portfolio Shares are subject to the standard corporation tax rate of 22% irrespective of ownership period.

The withholding tax rate is 22%. A claim for repayment must be filed within two months. Otherwise, the excess tax will be offset in the corporation income tax for the year. However, the withholding rate on dividends from Tax-Exempt Portfolio Shares is as of January 1, 2016 reduced to 15.4% if certain documentative requirements are met.

Dividends received on Subsidiary Shares and Group Shares are tax-exempt irrespective of ownership period.

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:

Double Taxation Treaty

In the event that the shareholder is a resident of a state with which Denmark has entered into a double taxation 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 treaty between Denmark and the United States generally provides for a 15% tax rate.

Credit under 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 double 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, why the shareholder must also in this situation claim a refund as described above in order to benefit from the reduced rate.

In addition, there is a special tax regime that applies to dividends distributed to individuals residing in certain countries, such as the United States, the United Kingdom, Belgium, Canada, Greece, the Netherlands, Ireland, Luxembourg, Norway, Switzerland, Sweden and Germany. This special tax regime provides that taxes on dividends may be withheld at the applicable tax rate specified in the relevant tax treaty. In order to qualify for the application of this special tax regime, an eligible holder of shares must deposit his shares with a Danish bank, and the shareholding must be registered with and administered through VP Securities A/S.

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 exempt from Danish withholding tax provided 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 withholding 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.

Dividend payments on both Tax-Exempt and Taxable Portfolio Shares will generally be subject to withholding tax at a rate of 27% irrespective of ownership period. 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:

Double Taxation Treaty

In the event that the shareholder is a resident of a state with which Denmark has entered into a double taxation 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 treaty between Denmark and the United States generally provides for a 15% rate.

Credit under 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 double taxation treaty or an international agreement, convention or other administrative agreement on assistance in tax according to which the competent authority in the state of the shareholder is obligated to exchange information with Denmark, dividends are generally subject to a tax rate of 15%. If the shareholder is tax resident outside the European Union, it is an additional requirement for eligibility for the 15% tax rate that the shareholder together with related shareholders holds less than 10% of the nominal share capital of the company. Note that the reduced tax rate does not affect the withholding rate, hence, in this situation the shareholder must also in this situation claim a refund as described above in order to benefit from the reduced rate.

Where a non-resident company of Denmark holds shares which can be attributed to a permanent establishment in Denmark, dividends are taxable pursuant to the rules applying to Danish tax residents described above.

Share Transfer Tax and Stamp Duties

No Danish share transfer tax or stamp duties are payable on transfer of the shares.

Material U.S. Federal Income Tax Consequences to U.S. Holders

The following discussion describes the material U.S. federal income tax consequences to U.S. Holders (as defined below) under present law of an investment in the ADSs. The effects of any applicable state or local laws, or other U.S. federal tax laws such as estate and gift tax laws, or the Medicare contribution tax on net investment income, are not discussed. This summary applies only to investors who hold the ADSs as capital assets (generally, property held for investment) and who have the U.S. dollar as their functional currency. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury regulations promulgated thereunder, judicial decisions, published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, and the income tax treaty between the United States and Denmark, or the Treaty, all as in effect as of the date of this annual report. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below.

The following discussion does not address all U.S. federal income tax consequences relevant to a holder's particular circumstances or to holders subject to particular rules, including:

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons whose functional currency is not the U.S. dollar;
- persons holding the ADSs as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;

- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities, commodities or currencies;
- partnerships, S corporations, or other entities or arrangements treated as partnerships for U.S. federal income tax purposes;
- tax-exempt organizations or governmental organizations;
- persons who acquired the ADSs pursuant to the exercise of any employee share option or otherwise as compensation;
- persons that own or are deemed to own 10% or more of our voting stock;
- persons that hold their ADSs through a permanent establishment or fixed base outside the United States; and
- persons deemed to sell our ADS under the constructive sale provisions of the Code.

U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE U.S. STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF THE ADSs.

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of the ADSs that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

If you are a partner in a partnership (or other entity taxable as a partnership for U.S. federal income tax purposes) that holds the ADSs, your tax treatment generally will depend on your status and the activities of the partnership. Partnerships holding the ADSs and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences applicable to them.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Generally, a holder of an ADS should be treated for the U.S. federal income tax purposes as holding the ordinary shares represented by the ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares. The U.S. Treasury has expressed concerns that intermediaries in the chain of ownership between the holder of an ADS and the issuer of the security underlying the ADS may be taking actions that are inconsistent with the beneficial ownership of the underlying security. Accordingly the creditability of foreign taxes, if any, as described below, could be affected by actions taken by intermediaries in the chain of ownership between the holders of ADSs and our company if as a result of such actions the holders of ADSs are not properly treated as beneficial owners of underlying ordinary shares.

Taxation of Dividends and Other Distributions on the ADSs

Subject to the PFIC rules discussed below, the gross amount of any distribution to you with respect to the ADSs will be included in your gross income as dividend income when actually or constructively received to the extent that the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent the amount of the distribution exceeds our current and accumulated earnings and profits, it will be treated first as a return of your tax basis in the ADSs, and to the extent the amount of the distribution exceeds your tax basis, the excess will be taxed as capital gain. We do not intend to calculate our earnings and profits under U.S. federal income tax principles. Therefore, a U.S. Holder should expect a distribution will generally be reported as ordinary dividend income for such purposes. Any dividends will not be eligible for the dividends-received deduction allowed to corporations in respect of dividends received from other U.S. corporations.

If we are eligible for benefits under the Treaty, dividends a U.S. Holder receives from us generally will be "qualified dividend income." If certain holding period and other requirements, including a requirement that we are not a PFIC in the year of the dividend or the immediately preceding year, are met, qualified dividend income of an individual or other non-corporate U.S. Holder generally will be subject to preferential tax rates. You should consult your tax advisor regarding the availability of this preferential tax rate 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" or "general 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, 2015. However, the application of the PFIC rules is subject to uncertainty in several respects, and we cannot assure you we will not be a PFIC for any taxable year. A non-U.S. corporation is considered a PFIC for any taxable year if either:

- at least 75% of its gross income for such taxable year is passive income, or
- at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income.

For purposes of the above calculations, if a non-U.S. corporation owns, directly or indirectly, 25% or more of the total value of the outstanding shares of another corporation, it will be treated as if it (a) held a proportionate share of the assets of such other corporation and (b) received directly a proportionate share of the income of such other corporation. Passive income generally includes dividends, interest, rents, royalties and capital gains, but generally excludes rents and royalties which are derived in the active conduct of a trade or business and which are received from a person other than a related person.

A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). Because the value of our assets for purposes of the asset test will generally be determined by reference to the market price of the ADSs, our PFIC status will depend in large part on the market price of the ADSs, which may fluctuate significantly. In addition, changes in the composition of our income or assets may cause us to become a PFIC.

If we are a PFIC for any year during which you hold the ADSs, we generally will continue to be treated as a PFIC with respect to you for all succeeding years during which you hold the ADSs, unless we cease to be a PFIC and you make a "deemed sale" election with respect to the ADSs you hold. If such election is made, you will be deemed to have sold the ADSs you hold at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be subject to the consequences described below. After the deemed sale election, the ADSs with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

For each taxable year we are treated as a PFIC with respect to you, you will be subject to special tax rules with respect to any "excess distribution" you receive and any gain you realize from a sale or other disposition (including a pledge) of the ADSs, unless you make a "mark-to-market" election as discussed below. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for the ADSs will be treated as an excess distribution. Under these special tax rules, if you receive any excess distribution or realize any gain from a sale or other disposition of the ADSs:

- the excess distribution or gain will be allocated ratably over your holding period for the ADSs,
- the amount allocated to the current taxable year, and any taxable year before the first taxable year in which we were a PFIC, will be treated as ordinary income, and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years before the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and 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 ordinary shares. 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 which are not PFICs would apply to distributions by us, except the lower applicable tax rate for qualified dividend income would not apply. If we cease to be a PFIC when you have a mark-to-market election in effect, gain or loss realized by you on the sale of the ADSs will be a capital gain or loss and taxed in the manner described above under "Taxation of Disposition of the ADSs."

The mark-to-market election is available only for "marketable stock," which is stock that is traded in other than *de minimis* quantities on at least 15 days during each calendar quarter, or regularly traded, on a qualified exchange or other market, as defined in applicable U.S. Treasury regulations. Any trades that have as their principal purpose meeting this requirement will be disregarded. The ADSs have been approved for listing on The NASDAQ Global Select Market and, accordingly, provided the ADSs are regularly traded, if you are a holder of ADSs, the mark-to-market election would be available to you if we are a PFIC. Once made, the election cannot be revoked without the consent of the IRS unless the ADSs cease to be marketable stock. If we are a PFIC for any year in which the U.S. Holder owns ADSs but before a mark-to-market election is made, the interest charge rules described above will apply to any mark-to-market gain recognized in the year the election is made. If any of our subsidiaries are or become PFICs, the mark-to-market election will not be available with respect to the shares of such subsidiaries that are treated as owned by you. Consequently, you could be subject to the PFIC rules with respect to income of the lower-tier PFICs the value of which already had been taken into account indirectly via mark-to-market adjustments. A U.S. Holder should consult its tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

In certain circumstances, a U.S. Holder of stock in a PFIC can make a "qualified electing fund election" to mitigate some of the adverse tax consequences of holding stock in a PFIC by including in income its share of the corporation's income on a current basis. However, we do not currently intend to prepare or provide the information that would enable you to make a qualified electing fund election.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules, taking into account the uncertainty as to whether we are currently treated as or may become a PFIC.

YOU ARE STRONGLY URGED TO CONSULT YOUR TAX ADVISOR REGARDING THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE ADSs.

Information Reporting and Backup Withholding

Dividend payments with respect to the ADSs and proceeds from the sale, exchange or other disposition of the ADSs may be subject to information reporting to the IRS and U.S. backup withholding. Certain U.S. Holders are exempt from backup withholding, including corporations and certain tax-exempt organizations. A U.S. Holder will be subject to backup withholding if such holder is not otherwise exempt and such holder:

- fails to furnish the holder's taxpayer identification number, which for an individual is ordinarily his or her social security number;
- furnishes an incorrect taxpayer identification number;
- is notified by the IRS that the holder previously failed to properly report payments of interest or dividends; or
- fails to certify under penalties of perjury that the holder has furnished a correct taxpayer identification number and that the IRS has not notified the holder that the holder is subject to backup withholding.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against the U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. U.S. Holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

Additional Reporting Requirements

Tax return disclosure obligations (and related penalties for failure to disclose) apply to certain U.S. Holders who hold certain specified foreign financial assets in excess of certain thresholds. The definition of specified foreign financial assets includes not only financial accounts maintained in foreign financial institutions, but also may include the ADSs. U.S. Holders should consult their tax advisors regarding the possible implications of these tax return disclosure obligations.

F. Dividends and Paying Agents

Not applicable.

G. Statements by Experts

Not applicable.

H. Documents on Display

We are subject to the periodic reporting and other informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under the Exchange Act, we are required to file reports and other information with the SEC. Specifically, we are required to file annually a Form 20-F no later than four months after the close of each fiscal year, which is December 31. Copies of reports and other information, when so filed, may be inspected without charge and may be obtained at prescribed rates at the public reference facilities maintained by the Securities and Exchange Commission at Judiciary Plaza, 100 F Street, N.E., Washington, D.C. 20549, and at the regional office of the Securities and Exchange Commission located at Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661. The public may obtain information regarding the Washington, D.C. Public Reference Room by calling the Commission at 1-800-SEC-0330. The SEC also 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 will also represent 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 will be administered is located at 101 Barclay Street, New York, New York 10286. The depositary's principal executive office is located at One Wall Street, New York, New York 10286.

A deposit agreement among us, the depositary and you the ADS holders sets out ADS holder rights as well as the rights and obligations of the depositary. A copy of the Agreement is incorporated by reference as an exhibit to this annual report.

Fees and Expenses

Pursuant to the terms of the deposit agreement, the holders of ADSs will be required to pay the following fees:

Persons depositing or withdrawing ordinary shares or ADSs must pay:	***For:***
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	• Issue of ADSs, including issues resulting from a distribution of ordinary shares or rights or other property • Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$0.05 (or less) per ADS	• Any cash distribution to you

A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the shares had been deposited for issue of ADSs	• Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to you
$0.05 (or less) per ADS per calendar year	• Depositary services
Registration or transfer fees	• Transfer and registration of ordinary shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	• Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement) • Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian have to pay on any ADS or share underlying an ADS, for example, share transfer taxes, stamp duty or withholding taxes	• As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	• As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing ordinary shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide for-fee services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse or share revenue from the fees collected from ADS holders, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the ADS program. In performing its duties under the deposit agreement, the depositary may use brokers, dealers or other service providers that are affiliates of the depositary and that may earn or share fees or commissions.

PART II

Item 13 *Defaults, Dividend Arrearages and Delinquencies*

Not applicable.

Item 14 *Material Modification to the Rights of Security Holders and Use of Proceeds*

A. Material Modifications to the Rights of Securities Holders

Not applicable.

B. Use of Proceeds

In February 2015, we sold 6,900,000 ADSs, each representing one ordinary share, nominal value DKK 1 per share, in our initial public offering at a public offering price of $18.00 per ADS, for aggregate gross proceeds to us of approximately $124.2 million. The net offering proceeds to us, after deducting underwriting discounts and

commissions totaling approximately $8.7 million and offering expenses totaling approximately $4.0 million, were approximately $111.5 million. The offering commenced on January 16, 2015 and did not terminate before all of the securities registered in the registration statement were sold. The effective date of the registration statement, File No. 333-201050, for our initial public offering of ADSs was January 27, 2015. Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Partners LLC acted as joint book-running managers of the offering and as representatives of the underwriters.

None of the payments described in this Item 14 were direct or indirect payments to our directors, officers, general partners or their associates, or any persons owning 10% or more of our ordinary shares, or our affiliates.

There has been no material change in the planned use of proceeds from our initial public offering, as described in our final prospectus filed with the SEC pursuant to rule 424(b) under the Securities Act on January 28, 2015.

Item 15 *Control and Procedures*

A. Disclosure Controls and Procedures

Our chief executive officer and principal financial and accounting officer, 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, 2015, 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 not effective due to the material weaknesses in internal control over financial reporting described below.

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, 2015. This assessment was performed under the directions and supervision of our Chief Executive Officer and our principal financial and accounting officer, and based on the criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission. Based on this assessment, management identified material weaknesses in our internal control over financial reporting. Firstly, a material error in research and development costs for the year ended December 31, 2015 was identified and corrected. Due to a material weakness in the design of our controls related to the recognition of costs for deliverables under our supplier agreements, research and development costs were overstated by an amount that should have been recognized in the following financial year. Secondly, we commenced but did not complete the

design and implementation of adequate internal controls relating to entity-level controls, controls over financial reporting and controls over our IT applications.

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 not effective as of December 31, 2015, based on the material weaknesses noted above.

We have developed a remediation plan to address the material weaknesses discussed above and to improve our internal controls over financial reporting. The plan includes increasing the resources we allocate to the review and interpretation of our agreements with suppliers and the deliverables under such agreements to ensure appropriate recognition of research and development costs. The plan also includes completing the documentation and testing of our entity-level controls, controls over financial reporting and controls over our IT applications to support management's assessment of our internal control over financial reporting.

C. Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting due to an exemption provided by the JOBS Act for emerging growth companies.

D. Changes in Internal Control over Financial Reporting

Other than the identification and planned remediation of the material weaknesses described above, 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. Martin Olin, an independent director and a member of the Audit Committee, qualifies as an "audit committee financial expert," as defined in Item 16A of Form 20-F and as determined by our board of directors.

Item 16B ***Code of Ethics***

We have adopted a code of business conduct and ethics that applies to all of our employees, members of our senior management and members of our board of directors, including those members of our senior management responsible for financial reporting. Our code of ethics is posted on our company website at: http://www.ascendispharma.com/ir. 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, 2015		Year ended December 31, 2014	
	EUR'000	%	EUR'000	%
Audit Fees	342	100%	334	30%
Audit-related Fees	—	—	789	70%
Tax Fees	—	—	—	—
All Other Fees	—	—	—	—
Total	**342**	**100%**	**1,123**	**100%**

Audit Fees are defined as the standard audit work that needs to be performed each year in order to issue opinions on our consolidated financial statements and to issue reports on our local statutory financial statements. Also included are services that can only be provided by our auditor, such as reviews of quarterly financial results, consents and comfort letters and any other audit services required for SEC or other regulatory filings.

Audit Related Fees include those other assurance services provided by the independent auditor but not restricted to those that can only be provided by the auditor signing the audit report.

Tax Fees relate to the aggregated fees for services rendered on tax compliance.

All Other Fees are any additional amounts billed for products and services provided by the principal accountant.

Pre-Approval Policies and Procedures for Non-Audit Services

Our Audit Committee has adopted a policy pursuant to which we will not engage our auditors to perform any non-audit services unless the audit committee pre-approves the service, effective for the period following the completion of our initial public offering. The policy was not in place during 2014.

Item 16D ***Exemptions From the Listing Standards for Audit Committees***

Not applicable.

Item 16E ***Purchases of Equity Securities by the Issuer and Affiliated Purchasers***

None.

Item 16F ***Change in Registrants Certifying Accountant***

None.

Item 16G ***Corporate Governance***

The Sarbanes-Oxley Act of 2002, as well as related rules subsequently implemented by the SEC, requires foreign private issuers, including our company, to comply with various corporate governance practices. In addition, NASDAQ rules provide that foreign private issuers may follow home country practice in lieu of the NASDAQ corporate governance standards, subject to certain exceptions and except to the extent that such exemptions would be contrary to U.S. federal securities laws. In addition to the home country practices described under Item 6.C of this annual report, the home country practices followed by our company in lieu of NASDAQ rules are described below:

- We do not intend to follow NASDAQ's quorum requirements applicable to meetings of shareholders. In accordance with Danish corporate law and generally accepted business practice, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders.
- We do not intend to follow NASDAQ's requirements regarding the provision of proxy statements for general meetings of shareholders. Danish corporate law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in Denmark. We do intend to provide shareholders with an agenda and other relevant documents for the general meeting of shareholders.

- We do not intend to follow NASDAQ's requirements regarding shareholder approval for certain issuances of securities under NASDAQ Rule 5635. Pursuant to Danish corporate law our shareholders have authorized our board of directors to issue securities including in connection with certain events such as the acquisition of shares or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us, rights issues at or below market price, certain private placements and issuance of convertible notes. We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act of 2002, the rules adopted by the SEC and NASDAQ's listing standards. As a Danish company not listed on a regulated market within the EU/EEA, we do not need to comply with the Danish corporate governance principles nor do we need to explain any deviation from these provisions in our Danish statutory annual report.
- We do not intend to follow NASDAQ's requirements regarding shareholder approval for all equity compensation plans. Generally, NASDAQ Rule 5635(c) requires each issuer to obtain shareholder approval of all equity compensation plans (including warrant incentive plans) and material amendments to such plans. However, pursuant to NASDAQ Rule 5615(a)(3), we have elected to follow our home country's practices (in this case, being Danish practices) in lieu of the requirements of NASDAQ Rule 5635(c). Our home country practices do not require us to obtain a shareholders' approval for amendments to our existing warrant incentive program.

Because we are a foreign private issuer, our members of our board of directors, executive board members and senior management are not subject to short-swing profit and insider trading reporting obligations under section 16 of the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act. They will, however, be subject to the obligations to report changes in share ownership under section 13 of the Exchange Act and related SEC rules.

Item 16H ***Mine Safety Disclosure***

Not applicable.

PART III

Item 17 ***Financial Statements***

See "Item 18 Financial Statements."

Item 18 ***Financial Statements***

See the Financial Statements beginning on page F-1.

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	3/18/2016	1.1	001-36815	
2.1	Deposit Agreement dated January 27, 2015 among Ascendis Pharma A/S The Bank of New York Mellon and Owners and Holders of American Depositary Shares.	F-3	2/2/2016	4.2	333-209336	
2.2	Form of American Depositary Receipt (included in Exhibit 2.1).					
4.1†	Exclusive Licence Agreement dated July 31, 2013 between Ascendis Pharma Ophthalmology Division A/S, Genentech, Inc. and F. Hoffmann-La Roche Ltd.	F-1	12/18/2014	10.1	333-201050	

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	Date	Number	File Number	
4.2†	Patent Transfer & Exclusive Licence Agreement dated December 15, 2010 between Ascendis Pharma A/S and Sanofi Aventis Deutschland GmbH.	F-1	12/18/2014	10.2	333-201050	
4.3(a)	Rental Agreement, between Technologiepark Heidelberg II GmbH & Co. KG and Ascendis Pharma GmbH (English translation).	F-1	12/18/2014	10.3(a)	333-201050	
4.3(b)	Supplement No. 1 to Rental Agreement, between Technologiepark Heidelberg II GmbH & Co. KG and Ascendis Pharma GmbH (English translation).	F-1	12/18/2014	10.3(b)	333-201050	
4.4(a)#	Reference is made to Exhibit 1.1.					
4.4(b)#	Form of Warrant Certificate for Warrants issued prior to December 2015.	F-1	12/18/2014	10.4(b)	333-201050	
4.4(c)#	Form of Warrant Certificate for Warrants issued since December 2015.					X
4.5#	Form of Indemnification Agreement for board members and senior management.	F-1	1/16/2014	10.5	333-201050	
4.6(a)	Registration Rights Agreement dated November 24, 2014 among Ascendis Pharma A/S and the investors set forth therein.	F-1	12/18/2014	10.6	333-201050	
4.6(b)	First Amendment to Registration Rights Agreement dated December 11, 2015 by and among Ascendis Pharma A/S and the investors set forth therein.	6-K	12/14/2015	4.2	001-36815	
4.7	Registration Rights Agreement dated December 11, 2015 by and among Ascendis Pharma A/S, Fidelity Securities Fund: Fidelity Series Small Cap Opportunities Fund—Healthcare Sub and Fidelity Stock Selector Small Cap Fund—Health Care Sub.	6-K	12/14/2015	4.1	001-36815	
4.8	Lease Agreement dated September 7, 2015 between Ascendis Pharma A/S and Dades AS.	F-3	2/2/2016	10.1	001-36815	
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 and Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					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.

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Signatures

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Ascendis Pharma A/S

By: /s/ Jan Møller Mikkelsen
Jan Møller Mikkelsen
President, Chief Executive Officer, Board Member and Executive Director (Principal Executive Officer)

Date: April 15, 2016

By: /s/ Peter Rasmussen
Peter Rasmussen
VP Finance (Principal Financial and Accounting Officer)

Date: April 15, 2016

Notes to the Consolidated Financial Statements

ASCENDIS PHARMA A/S

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Ascendis Pharma A/S
Hellerup, Denmark

We have audited the accompanying consolidated statements of financial position of Ascendis Pharma A/S and subsidiaries (the "Company") as of December 31, 2015 and December 31, 2014, and the 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, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Ascendis Pharma A/S and subsidiaries as of December 31, 2015 and December 31, 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Deloitte Statsautoriseret Revisionspartnerselskab
CVR no. 33963556
Copenhagen, April 14, 2016

/s/ Jens Sejer Pedersen
State Authorised
Public Accountant

/s/ Flemming Larsen
State Authorised
Public Accountant

Notes to the Consolidated Financial Statements

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

	Notes	2015	2014	2013
			(EUR'000)	
Revenue	4	8,118	13,983	20,408
Research and development costs		(40,528)	(19,698)	(12,713)
General and administrative expenses		(9,415)	(6,274)	(2,416)
Operating profit/(loss)		**(41,825)**	**(11,989)**	**5,279**
Finance income	7	11,048	1,877	158
Finance expenses	7	(2,797)	(228)	(732)
Profit/(loss) before tax		**(33,574)**	**(10,340)**	**4,705**
Tax on profit/(loss) for the year	8	652	682	(626)
Net profit/(loss) for the year		**(32,922)**	**(9,658)**	**4,079**
Other comprehensive income/(loss)				
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translating foreign operations		(14)	(14)	(6)
Other comprehensive loss for the year, net of tax		**(14)**	**(14)**	**(6)**
Total comprehensive income/(loss) for the year, net of tax		**(32,936)**	**(9,672)**	**4,073**
Profit/(loss) for the year attributable to owners of the Company		(32,922)	(9,658)	4,079
Total comprehensive income/(loss) for the year attributable to owners of the Company		(32,936)	(9,672)	4,073
		EUR	EUR	EUR
Basic earnings/(loss) per share		(1.39)	(0.85)	0.38
Diluted earnings/(loss) per share		(1.39)	(0.85)	0.32
Number of shares used for calculation (basic)		23,766,783	11,406,929	10,801,948
Number of shares used for calculation (diluted)(1)		23,766,783	11,406,929	12,825,908

(1) A total of 2,615,903 warrants outstanding as of December 31, 2015 (a total of 2,999,824 warrants outstanding as of December 31, 2014) 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.

Notes to the Consolidated Financial Statements

Consolidated Statements of Financial Position As of December 31,

	Notes	2015	2014
		(EUR'000)	
Assets			
Non-current assets			
Intangible assets	**9**	3,495	3,495
Property, plant and equipment	**10**	2,355	1,874
Deposits		270	140
		6,120	**5,509**
Current assets			
Trade receivables		1,064	1,292
Other receivables		338	210
Prepayments		3,819	620
Income taxes receivable	**8**	784	873
Cash and cash equivalents		119,649	50,167
		125,654	**53,162**
Total assets		**131,774**	**58,671**
Equity and liabilities			
Equity			
Share capital	**12**	3,374	2,272
Other reserves	**13**	5,678	3,979
Retained earnings		111,277	39,559
Total equity		**120,329**	**45,810**
Current liabilities			
Trade payables and other payables		8,373	4,956
Deferred income	**14**	3,072	7,905
		11,445	**12,861**
Total liabilities		**11,445**	**12,861**
Total equity and liabilities		**131,774**	**58,671**

Notes to the Consolidated Financial Statements

Consolidated Statements of Changes in Equity

	Share Capital	Foreign Currency Translation Reserve	Share-based Payment Reserve	Retained Earnings	Total
			(EUR'000)		
Equity at January 1, 2013	**1,448**	**(51)**	**2,105**	**(1,946)**	**1,556**
Profit for the year	—	—	—	4,079	**4,079**
Other comprehensive loss, net of tax	—	(6)	—	—	**(6)**
Total comprehensive income/(loss)	—	**(6)**	—	**4,079**	**4,073**
Share-based payment (Note 6)	—	—	671	—	**671**
Equity at December 31, 2013	**1,448**	**(57)**	**2,776**	**2,134**	**6,301**
Loss for the year	—	—	—	(9,658)	**(9,658)**
Other comprehensive loss, net of tax	—	(14)	—	—	**(14)**
Total comprehensive income/(loss)	—	**(14)**	—	**(9,658)**	**(9,672)**
Share-based payment (Note 6)	—	—	1,274	—	**1,274**
Capital increase	824	—	—	47,272	**48,096**
Cost of capital increase	—	—	—	(189)	**(189)**
Equity at December 31, 2014	**2,272**	**(71)**	**4,050**	**39,559**	**45,810**
Loss for the year	—	—	—	(32,922)	**(32,922)**
Other comprehensive loss, net of tax	—	(14)	—	—	**(14)**
Total comprehensive income/(loss)	—	**(14)**	**—**	**(32,922)**	**(32,936)**
Share-based payment (Note 6)	—	—	1,713	—	**1,713**
Capital increase	1,102	—	—	113,036	**114,138**
Cost of capital increase	—	—	—	(8,396)	**(8,396)**
Equity at December 31, 2015	**3,374**	**(85)**	**5,763**	**111,277**	**120,329**

Notes to the Consolidated Financial Statements

Consolidated Cash Flow Statements for the year Ended December 31

	2015	2014	2013
		(EUR'000)	
Operating activities			
Net profit/(loss) for the year	**(32,922)**	**(9,658)**	**4,079**
Reversal of finance income	(11,048)	(1,877)	(158)
Reversal of finance expenses	2,797	228	732
Reversal of tax charge	(652)	(682)	626
Adjustments for:			
Share-based payment	1,713	1,274	671
Depreciation and amortization	558	504	405
Changes in working capital:			
Deposits	(130)	(108)	(2)
Trade receivables	228	413	4,013
Other receivables	(128)	(210)	353
Prepayments	(3,199)	(556)	26
Trade payables and other payables	3,403	2,622	(12)
Deferred income	(4,833)	(9,565)	(3,614)
Income taxes payable	—	—	(239)
Cash flows generated from/(used in) operations	**(44,213)**	**(17,615)**	**6,880**
Finance income received	13	182	115
Finance expenses paid	(6)	(171)	(685)
Income taxes received / (paid)	740	(799)	—
Cash flows from/(used in) operating activities	**(43,466)**	**(18,403)**	**6,310**
Investing activities			
Acquisition of property, plant and equipment	(1,039)	(405)	(1,195)
Cash flows used in investing activities	**(1,039)**	**(405)**	**(1,195)**
Financing activities			
Capital increase	114,138	48,096	—
Cost of capital increase	(8,396)	(189)	—
Installments on long-term financial liabilities	—	—	(220)
Cash flows from / (used in) financing activities	**105,742**	**47,907**	**(220)**
Increase / (decrease) in cash and cash equivalents	**61,237**	**29,099**	**4,895**
Cash and cash equivalents at January 1	50,167	19,430	14,535
Effect of exchange rate changes on balances held in foreign currencies	8,245	1,638	—
Cash and cash equivalents at December 31	**119,649**	**50,167**	**19,430**

Notes to the Consolidated Financial Statements

Note 1—General Information

Ascendis Pharma A/S, together with its subsidiaries, is a clinical stage biopharmaceutical company applying its TransCon technology to develop a pipeline of therapeutics with best-in-class profiles addressing unmet medical needs. Ascendis Pharma A/S was incorporated in 2006 and is headquartered in Hellerup, Denmark. Unless the context otherwise requires, references to the "Company," "Ascendis," "we," "us" and "our" refer to Ascendis Pharma A/S and its subsidiaries.

The address of its registered office is Tuborg Boulevard 5, DK-2900 Hellerup.

On February 2, 2015, the Company completed an initial public offering, or IPO, which resulted in the listing of American Depository Shares representing the Company's ordinary shares, under the symbol "ASND" in the United States on the NASDAQ Global Select Market.

The Company's board of directors approved these consolidated financial statements on April 14, 2016.

Note 2—Summary of Significant Accounting Policies

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. Unless otherwise stated, these policies have been applied consistently to all years presented. Significant accounting estimates used when exercising the accounting policies are described in Note 3.

The accounting policies are consistent with those of the previous year.

Our consolidated financial statements have been prepared under the historical cost convention, apart from certain financial instruments that are measured at fair value at initial recognition.

Going Concern

The Company's Board of Directors has, at the time of approving the financial statements, a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Thus, we continue to adopt the going concern basis of accounting in preparing the financial statements.

Retrospective Effect of Bonus Share Issuance

All share and per share data in the consolidated financial statements give retroactive effect to a bonus issue of shares in the ratio of 3:1 of the Company's authorized, issued and outstanding ordinary and preference shares, which was effective on January 13, 2015, with the corresponding impacts on both share capital and retained earnings also retroactively recognized. Retrospective effect has also been given with respect to the share and per share data for the warrants.

Recognition and Measurement

Assets are recognized in the consolidated statement of financial position when it is probable, as a result of a prior event, that future economic benefits will flow to us and the value of the asset can be measured reliably.

Liabilities are recognized in the consolidated statement of financial position when we have a legal or constructive obligation as a result of a prior event, and it is probable that future economic benefits will flow from us and the value of the liability can be measured reliably.

Notes to the Consolidated Financial Statements

On initial recognition, assets and liabilities are measured at cost or at fair value, depending on the classification of the items. Measurement subsequent to initial recognition is affected as described below for each financial statement item. Anticipated risks and losses that arise before the time of presentation of the consolidated financial statements and that confirm or invalidate affairs and conditions existing at the consolidated statement of financial position date are considered at the time of recognition and measurement.

Income is recognized in the consolidated statement of profit or loss when earned, whereas costs are recognized by the amounts attributable to the financial year.

Basis of Consolidation

The consolidated financial statements include our parent company, Ascendis Pharma A/S, and all entities over which the parent company has control. We control an entity when we are exposed to, or have rights to, variable returns from our involvement with the entity and have the ability to control those returns through our power over the entity. Accordingly, the consolidated financial statements include Ascendis Pharma A/S and the entities listed in Note 11.

Consolidation Principles

Our subsidiaries are fully consolidated from the date upon which control is transferred to us. They are deconsolidated from the date control ceases.

When necessary, adjustments are made to the financial statements of our subsidiaries to conform their accounting policies to our accounting policies. All intra-company assets and liabilities, equity, income, expenses and cash flows relating to transactions between our group enterprises are eliminated in full upon consolidation.

Foreign Currency

On initial recognition, transactions in currencies other than an individual company's functional currency are translated applying the exchange rate in effect at the date of the transaction. Receivables, payables and other monetary items denominated in foreign currencies that have not been settled at the balance sheet date are translated using the exchange rate in effect at the balance sheet date.

Exchange differences that arise between the rate at the transaction date and the rate in effect at the payment date, or the rate at the balance sheet date, are recognized in profit or loss as financial income or financial expenses. Property, plant and equipment, intangible assets and other non-monetary assets purchased in foreign currencies and measured on the basis of historical cost are translated at the transaction date exchange rate.

When subsidiaries that present their financial statements in a functional currency other than EUR are recognized in the consolidated financial statements, the statements of profit or loss are translated at average exchange rates. Balance sheet items are translated using the exchange rates at the balance sheet date. Exchange differences arising out of the translation of foreign entities' balance sheet items at the beginning of the year using the balance sheet date exchange rates as well as out of the translation of statements of profit or loss from average rates to the exchange rates at the balance sheet date are recognized in other comprehensive income. Similarly, exchange differences arising out of changes that have been made directly in a foreign subsidiary's equity are recognized in other comprehensive income.

Business Combinations

Newly acquired or newly established subsidiaries are recognized in the consolidated financial statements from the time of acquiring or establishing such enterprises. Time of acquisition is the date on which control of the enterprise is actually acquired.

When acquiring new enterprises over which we obtain control, the acquisition method is applied. Under this method, we identify assets, liabilities and contingent liabilities of these enterprises and measure them at fair value at the acquisition date. Restructuring costs are only recognized in the pre-acquisition balance sheet if they constitute a liability of the acquired enterprise. Allowance is made for the tax effect of the adjustments made.

Notes to the Consolidated Financial Statements

The acquisition consideration for an enterprise consists of the fair value of the consideration paid for the acquired enterprise. If the final determination of the consideration is conditional upon one or several future events, they are recognized at fair value thereof at the time of acquisition. Costs that are attributable to the acquisition of the enterprise are recognized in 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.

Revenue

Our revenue currently comprises up-front payments and service fees from research, development and commercialization agreements. Our collaboration agreements comprise elements of up-front license fees, milestone payments based on development and sales and royalties based on product sales. In addition, our collaboration agreements contemplate our involvement in the ongoing research and development of our partnered product candidates, for which we are separately remunerated for the services we render.

As a general principle, revenue is recognized when it is probable that future economic benefits will flow to us and these benefits can be measured reliably. Further, revenue recognition requires that all significant risks and rewards of ownership of the goods or services included in the transaction have been transferred to the buyer, and that we retain neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods or services sold.

Collaboration agreements which contain multiple activities are only separated into individual units of accounting if they constitute a separate earnings process. If multiple activities or rights are not separable, they are combined into a single unit of accounting, and recognized over the period of continued involvement; i.e. the period where we are actively involved in development and deliver significant services to the collaboration partner. If multiple activities or rights are separable, each separate component is accounted for after considering the specific nature of the element and the underlying activities to which earnings process relates. For the three years ended December 31, 2015, 2014 and 2013, the collaboration agreements entered into by the Company did not meet the criteria for separation, and all arrangements were accounted for as a single unit of account. Accordingly, the up-front license payments have been recognized as revenue over the period of continued involvement. In addition, the milestone criteria and sales-based royalty thresholds have not yet been met and such thresholds are not yet considered probable, accordingly no milestone and royalty payments have been received or are expected to be received.

If we are entitled to reimbursement from our collaborators for specified research and development expenses and/or entitled to payments for specified research and development services that we provide, we determine whether the research and development funding would result in collaborative revenues or an offset to research and development expenses. Where the payment is for specific research and development services that are to be accounted for as collaborative revenue, such revenue is recognized when such services are provided. Where such payments are not to be considered to be collaborative revenue but are considered to be reimbursements for external expenses incurred, the reimbursements are offset against research and development costs.

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

Revenue is measured at fair value of the consideration received or receivable. Revenue is stated net of value added tax, duties, etc. collected on behalf of a third party and discounts.

Research and Development Costs

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

Notes to the Consolidated Financial Statements

Government grants received to cover expenses incurred are recognized in research and development costs.

Research costs are recognized in the consolidated statement of profit or loss in the period to which they relate. Development costs are recognized in the consolidated statement of profit or loss when incurred if the criteria for capitalization have not been met.

A development project involves a single product candidate undergoing a series of studies to illustrate its safety profile and effect on human beings prior to obtaining the necessary approval from the appropriate authorities. Due to the risk related to the development of pharmaceutical products, we cannot estimate the future economic benefits associated with individual development projects with sufficient certainty until the development project has been finalized and the necessary market approval of the final product has been obtained. As a consequence, all development costs are recognized in the consolidated statement of profit or loss in the period to which they relate.

General and Administrative Expenses

General and administrative expenses comprise salaries, share-based payment, and other staff costs including pensions, office supplies, cost of premises, and depreciation and amortization related to administrative activities.

General and administrative expenses are recognized in the consolidated statement of profit or loss in the period to which they relate.

Government Grants

Government grants are recognized when there is reasonable assurance that the conditions underlying the grants have been met and that the grant will be received. Government grants to cover expenses incurred are recognized in profit or loss proportionally over the periods during which the related expenses are recognized in profit or loss. The grants are off-set against the expenses incurred and thus reduce our research and development costs.

Share-based Incentive Programs

Share-based incentive programs under which board members, employees and external consultants have the option to purchase shares in Ascendis Pharma A/S (equity-settled share-based payment arrangements) are measured at the equity instrument's fair value at the grant date.

The cost of equity-settled transactions is determined by the fair value at the date of grant using the Black-Scholes valuation model. The cost is recognized together with a corresponding increase in equity over the period in which the performance and/or service conditions are fulfilled, the vesting period. The fair value determined at the grant date of the equity-settled share-based payment is expensed on a straight line basis over the vesting period for each tranche, based on our best estimate of the number of equity instruments that will ultimately vest. No expense is recognized for grants that do not ultimately vest.

Where an equity-settled grant is cancelled, it is treated as if it vested on the date of the cancellation, and any expense not yet recognized for the grant is recognized immediately. This includes any grant where non-vesting conditions within the control of either the entity or the employee are not met. However, if a new grant is substituted for the cancelled grant, and designated as a replacement grant on the date that it is granted, the cancelled and new grants are treated as if they were a modification of the original grant, as described in the previous paragraph. All cancellations of equity-settled transaction grants are treated equally.

Any social security contributions payable in connection with the grant or exercise of the warrants are recognized as incurred.

The assumptions used for estimating the fair value of share-based payment transactions are disclosed in Note 6.

Notes to the Consolidated Financial Statements

Finance Income and Expenses

Finance income and expenses comprise interest income and expenses, the interest portion related to finance lease contracts and realized and unrealized exchange rate gains and losses on transactions denominated in foreign currencies.

Interest income and interest expenses are stated on an accrual basis using the principal and the effective interest rate. The effective interest rate is the discount rate that is used to discount expected future payments related to the financial asset or the financial liability in order for the present value of such asset or liability to match their carrying amount.

Income Taxes

Tax for the year, which consists of current tax for the year and changes in deferred tax, is recognized in profit or loss by the portion attributable to the profit or loss for the year and recognized directly in equity or other comprehensive income by the portion attributable to entries directly in equity and in other comprehensive income. The current tax payable or receivable is recognized in the balance sheet, stated as tax computed on this year's taxable income, adjusted for prepaid tax.

When computing the current tax for the year, the tax rates and tax rules enacted or substantially enacted at the balance sheet date are used.

Deferred tax is recognized according to the balance sheet liability method of all temporary differences between carrying amounts and tax-based values of assets and liabilities, apart from deferred tax on all temporary differences occurring on initial recognition of goodwill or on initial recognition of a transaction which is not a business combination, and for which the temporary difference found at the time of initial recognition neither affects net profit or loss nor taxable income.

Deferred tax liabilities are recognized on all temporary differences related to investments in our subsidiaries, unless we are able to control when the deferred tax is realized, and it is probable that the deferred tax will not become due and payable as current tax in the foreseeable future.

Deferred tax is calculated based on the planned use of each asset and the settlement of each liability, respectively.

Deferred tax is measured using the tax rates and tax rules in the relevant countries that, based on acts in force or acts in reality in force at the balance sheet date, are expected to apply when the deferred tax is expected to crystallize as current tax. Changes in deferred tax resulting from changed tax rates or tax rules are recognized in profit or loss unless the deferred tax is attributable to transactions previously recognized directly in equity or other comprehensive income. In the latter case, such changes are also recognized in equity or other comprehensive income.

Deferred tax assets, including the tax base of tax loss carry forwards, are recognized in the balance sheet at their estimated realizable value, either as a set-off against deferred tax liabilities or as net tax assets for offset against future positive taxable income. At every balance sheet date, it is assessed whether sufficient taxable income is likely to arise in the future for the deferred tax asset to be used.

Intangible Assets

Goodwill

Goodwill is initially measured at cost, being the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests over the net identifiable assets acquired and liabilities assumed. After initial recognition, goodwill is measured at cost less any accumulated impairment losses. Goodwill is not amortized but is subject to impairment testing at least on a yearly basis. For the purpose of impairment testing, goodwill acquired in a business combination is allocated to each of the cash-generating units, or group of cash-generating units, that are expected to benefit from the synergies of the combination. Each cash-generating unit or group of cash generating units to which goodwill is allocated represent the lowest level within the Company at which the goodwill is monitored for internal management purposes. Goodwill is monitored at the consolidated level.

Notes to the Consolidated Financial Statements

Property, Plant and Equipment

Property, plant and equipment is measured at cost less accumulated depreciation and impairment losses. Cost comprises the acquisition price, costs directly attributable to the acquisition and preparation costs of the asset until the time when it is ready to be put into operation. For assets held under finance leases, cost is the lower of the asset's fair value and net present value of future lease payments.

Subsequent costs are included in the carrying amount of the asset or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the assets will flow to us and the costs of the items can be measured reliably. All repair and maintenance costs are charged to the consolidated statement of profit or loss during the financial periods in which they are incurred.

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 of depreciation is cost less estimated residual value. The residual value is the estimated amount that would be earned if selling the asset today net of selling costs, assuming that the asset is of an age and a condition that is expected after the end of its useful life. The cost of a combined asset is divided into smaller components, with such components depreciated individually if their useful lives vary.

Depreciation is calculated on a straight-line basis from the following assessment of an asset's expected useful life:

Process plant and machinery	5 - 10 years
Other fixtures and fittings, tools and equipment	3 - 5 years
Leasehold improvements	3 - 5 years

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

Property, plant and equipment are written down to the lower of recoverable amount and carrying amount, as described in the "Impairment" section below.

Depreciation, impairment losses and gains and losses on disposal of property, plant and equipment are recognized in the statements of profit or loss as research and development costs or as general and administrative expenses, as appropriate.

Impairment

Property, plant and equipment and finite-lived intangible assets are reviewed for impairment whenever events or circumstances indicate that the carrying amount may not be recoverable. The recoverable amount of goodwill is estimated annually irrespective of any recorded indications of impairment.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purpose of assessing impairment, assets are grouped at the lowest levels for which there are largely independent cash inflows, or cash-generating units, which for goodwill represent the lowest level within the entity 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. Receivables are classified as loans and receivables constituting financial assets with fixed or determinable payments that are not listed on an active market and are not derivative financial instruments.

Notes to the Consolidated Financial Statements

On initial recognition, receivables are measured at fair value and, subsequently, at amortized cost, usually equaling nominal value less a provision for bad debts. Provisions for bad debts are determined on the basis of an individual assessment of each receivable and recognized using an allowance account.

Prepayments

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

Cash and Cash Equivalents

Cash and cash equivalents comprise cash and demand deposits with financial institutions. Cash and cash equivalents are measured at fair value.

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.

Translation reserves include exchange rate adjustments of equity investments in our group enterprises.

Reserve for share-based payment represents the corresponding entries to the share-based payment recognized in the profit or loss, arising from our warrant programs.

Provisions

Provisions are recognized when we have an existing legal or constructive obligation as a result of events occurring prior to or on the balance sheet date, and it is probable that the utilization of economic resources will be required to settle the obligation. Provisions are measured as the best estimate of the expense necessary to settle the obligation at the balance sheet date. Provisions that are estimated to mature after more than one year after the balance sheet date are measured at their present values.

Leases

Leases of property, plant and equipment, where we have substantially all of the risks and rewards of ownership, are classified as finance leases. Other leases are classified as operating leases.

Assets held under finance leases are recognized in the balance sheet at the inception of the lease term at the lower of the fair value of the asset or the net present value of the future minimum lease payments. A liability equaling the asset is recognized in the balance sheet, allocated between non-current and current liabilities. Each lease payment is separated between an interest element, recognized as a financial expense, and a reduction of the lease liability.

Assets held under finance leases are depreciated over the shorter of the asset's useful life and the lease term.

Lease payments on operating leases are recognized on a straight-line basis in profit or loss over the term of the lease.

Total commitment under operating leases is disclosed in the notes to the consolidated financial statements.

Other Financial Liabilities

Other financial liabilities comprise trade payables, payables to public authorities and accrued expenses.

On initial recognition, other financial liabilities are measured at fair value less any transaction costs. Subsequently, these liabilities are measured at amortized cost applying the effective interest method to the effect that the difference between proceeds and nominal amount is recognized in the consolidated statement of profit or loss as a financial expense over the term of the liability.

Notes to the Consolidated Financial Statements

Deferred Income

Deferred income comprises income received for recognition in subsequent financial years. Deferred income typically arises from up-front payments under our collaboration agreements related to license grants or up-front funding of development activities. If we are participating in continued development of product candidates, up-front payments are recognized as deferred income and recognized as revenue over the anticipated period in which we are involved in the development activities. Deferred income is measured at the fair value of the income received.

Cash Flow Statement

The cash flow statement shows cash flows from operating, investing and financing activities as well as cash and cash equivalents at the beginning and the end of the financial year.

Cash flows from operating activities are presented using the indirect method and calculated as the profit or loss adjusted for non-cash items, working capital changes as well as financial income, financial expenses and income taxes paid.

Cash flows from investing activities comprise payments in connection with acquisitions, development, improvement and sale, etc. of intangible assets, property, plant and equipment, and group enterprises.

Cash flows from financing activities comprise changes in the share capital of Ascendis Pharma A/S and related costs as well as the raising and repayment of loans and installments on interest-bearing debt. Cash flows from financing activities also include lease payments made on assets held under finance leases.

The effect of exchange rates changes on cash and cash equivalents held or due in a foreign currency is presented separately from cash flows from operating, investing and financing activities.

Cash flows in currencies other than the functional currency are recognized in the cash flow statement, using the average exchange rates.

Cash and cash equivalents comprise cash at hand and deposits with financial institutions.

Segment Reporting

We are managed and operated as one operating and reportable segment. No separate operating segments or reportable segments have been identified in relation to product candidates or geographical markets. Accordingly, we do not disclose segment information on business segments or geographical markets.

Basic EPS

Basic Earnings per Share, or EPS, is calculated as the net income or loss from continuing operations for the period divided by the weighted average number or ordinary shares outstanding.

Diluted EPS

Diluted earnings per share is calculated as the 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 statement of profit or loss shows a net loss, no adjustment is made for the dilutive effect, as such effect would be anti-dilutive.

Notes to the Consolidated Financial Statements

New International Financial Reporting Standards and Interpretations Not Yet Effective

The IASB has issued, and the European Union has adopted, a number of new or amended standards and interpretations, which have not yet become effective. Therefore, these new standards and interpretations have not been incorporated in these consolidated financial statements. Our financial reporting is expected to be affected by such new or improved standards to the extent described below.

- In July 2014, IASB issued the final version of IFRS 9, "Financial Instruments". IFRS 9 brings together the classification and measurement, impairment and hedge accounting phases of the IASB's project to replace IAS 39, "Financial Instruments: Recognition and Measurement" and is expected to be effective for annual periods beginning on or after January 1, 2018. The standard awaits EU Endorsement. We do not believe that the application of IFRS 9 in the future will have a material impact on amounts reported in respect of the Company's financial assets and liabilities, but the final conclusion on this awaits a more detailed review of the standard.
- In May 2014, IASB issued IFRS 15 "Revenue from Contracts with Customers". The standard is part of the convergence project with FASB to replace IAS 18 "Revenue". The new standard will establish a single, comprehensive framework for revenue recognition, based on a five-step model to determine when, how and at what amount revenue is to be recognized depending on whether certain criteria are met. The standard awaits EU Endorsement. The initial effective date was January 1, 2017, but in September 2015, the IASB deferred the effective date to January 1, 2018. We do not believe that the application of IFRS 15 in the future will have a material impact on amounts reported in respect of the Company's revenues, but the final conclusion on this awaits a more detailed review of the standard.
- In January 2016, the IASB issued IFRS 16 "Leases", which requires lessees to recognize assets and liabilities for most leases. For lessors, there is little change to the existing accounting in IAS 17 "Leases". The standard awaits EU Endorsement. The new standard will be effective for annual periods beginning on or after January 1, 2019. We believe that the application of IFRS 16 will impact the Company's balance sheet through recognition of assets and liabilities that would currently not be recognized under the current standard, as they are classified as operating lease arrangements.

Note 3—Critical Accounting Judgments and Key Sources of Estimation Uncertainty

In the application of our accounting policies, we are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

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

Critical Judgments in Applying Accounting Policies

The following are the critical judgments, apart from those involving estimates, see below, made in the process of applying our accounting policies and that have the most significant effect on the amounts recognized in our consolidated financial statements.

Revenue Recognition

IAS 18, "Revenues" prescribes the criteria to be fulfilled for revenue being recognizable. Evaluating the criteria for revenue recognition with respect to our research and development and commercialization agreements requires judgment to ensure that all criteria have been fulfilled prior to recognizing any amount of revenue. We generate revenue from collaboration agreements which typically involve multiple elements, including licenses to our technology, transfer of patents, participation in joint development projects with our collaboration partners, and other services in various areas related to the development of new products. As part of evaluating the criteria for revenue recognition, we consider the separability of the individual deliverables in the collaboration agreements and potential allocation of the total consideration received to the individual elements of the agreement. Further, if any up-front elements are considered inseparable from a following development period, the appropriate allocation of an up-front payment over time needs to be determined.

Notes to the Consolidated Financial Statements

We evaluate all of our revenue generating transactions to ensure recognition in accordance with IFRS.

We have not signed any new collaboration agreements with external partners in 2015 or 2014.

In 2013, we signed an exclusive license agreement with Genentech within the field of ophthalmology. The agreement included an up-front payment and funding of research and development activities and entitles us to receive future development milestone payments and royalties on sales of licensed products. As the license granted to Genentech was interrelated to the agreed research and development activities, the deliverables were inseparable under IAS 18 and, accordingly, the up-front payment was recognized as deferred income to be recognized as revenue over the agreed research and development period.

In total, we had €3.1 million in deferred income as of December 31, 2015 compared to €7.9 million as of December 31, 2014.

Share-Based Payment

IFRS 2, "Share-Based Payment" requires an entity to reflect in its profit or loss and financial position the effects of share-based payment transactions, including expenses associated with transactions in which share options are granted to employees. We have granted warrants to employees, consultants and board members under three different programs as described in Note 6, which are accounted for under IFRS 2.

We use the Black-Scholes option-pricing model to value the warrants granted and critical judgments need to be exercised in determining the appropriate input to the valuation model as well as to determine the appropriate way of recognizing the expenses under IFRS 2.

Warrants granted under our warrant programs vest on a monthly basis over periods of up to 48 months. Due to the graded vesting, the related expenses are recognized on an accelerated basis; i.e. each tranche of a warrant grant is treated separately for expense recognition purposes. Accordingly, each warrant grant is treated in up to 48 tranches, which are each recognized over the expected useful life of that particular tranche. In total €1.7 million was recognized as share-based payment in the consolidated financial statements for 2015 compared to €1.3 million for 2014 and €0.7 million for 2013.

See Note 6 for additional details on our warrant programs and recognition of expenses under IFRS 2.

Internally Generated Intangible Assets

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

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

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

Joint Arrangements / Collaboration Agreements

Collaboration agreements within our industry are often structured so that each party contributes its respective skills in the various phases of a development project. No joint control exists for such collaborations and the parties do not have any financial obligations on behalf of each other. Accordingly, our collaborations are not considered to be joint arrangements as defined in IFRS 11, "Joint Arrangements".

Notes to the Consolidated Financial Statements

Key Sources of Estimation Uncertainty

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

Impairment of Goodwill

Determining whether goodwill is impaired requires an estimation of the recoverable amount, being the higher of fair value less costs of disposal or value in use, of the cash-generating units to which goodwill has been allocated. The recoverable amount of the cash-generating units is determined based on an estimation of the Company's fair value less costs of disposal. We have determined the fair value of goodwill after taking into account the market value of our ADSs representing the enterprise value of our group enterprises as of the balance sheet date. No impairment loss has been recognized in 2015 or 2014. The carrying amount of goodwill at December 31, 2015 and 2014 was €3.5 million. See note 9 for further details.

Recognition of Accruals for Manufacturing and Clinical Trial Activities

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

Useful Lives of Property, Plant and Equipment and Finite-Lived Intangible Assets

We review the estimated useful lives of property, plant and equipment and finite-lived intangible assets at the end of each reporting period. We have concluded that the useful lives applied for 2015, 2014 and 2013 are appropriate.

Except for the above areas, assumptions and estimates are not considered to be critical to the consolidated financial statements. No estimates or judgments have been made involving a material risk of significant adjustments of the assets or liabilities at the balance sheet date.

Note 4—Revenue

	2015	2014	2013
		(EUR'000)	
Revenue from the rendering of services	3,192	6,074	4,161
License income	4,926	7,909	16,247
Total revenue	**8,118**	**13,983**	**20,408**
Revenue from external customers (geographical)			
USA	7,350	11,024	10,965
Germany	487	2,959	9,443
Switzerland	281	—	—
Total revenue	**8,118**	**13,983**	**20,408**

Note 5—Segment Information

We are managed and operated as one business unit. No separate business areas or separate business units have been identified in relation to product candidates or geographical markets. Accordingly, we do not disclose information on business segments or geographical markets, except for the geographical information on revenue included in Note 4 and the information regarding major customers included below.

In the consolidated financial statements for 2015, one single customer accounts for more than 10% of total revenue. The revenue from this customer amounts to €7.4 million (91%).

Notes to the Consolidated Financial Statements

In the consolidated financial statements for 2014, three single customers each account for more than 10% of total revenue. The revenue from each customer amounts to €7.8 million (56%); €3.2 million (23%); and €3.0 million (21%), respectively.

In the consolidated financial statements for 2013, three single customers each account for more than 10% of total revenue. The revenue from each customer amounts to €9.4 million (46%); €7.4 million (36%); and €3.6 million (18%), respectively.

Note 6—Staff Cost

	2015	2014	2013
		(EUR'000)	
Wages and salaries	9,211	6,758	4,773
Share-based payment	1,713	1,274	671
Pension costs	42	38	35
Social security costs	697	501	427
Total salary expenses	**11,663**	**8,572**	**5,906**
Compensation to Key Management Personnel			
Wages and salaries	1,397	866	497
Share-based payment	508	582	251
Social security costs	74	61	37
Total compensation to Key Management Personnel	**1,979**	**1,509**	**785**
Average number of employees	**63**	**53**	**45**

Share-based payment

Ascendis Pharma A/S has established warrant programs, equity-settled share-based payment transactions, as an incentive for all of our employees, members of our board of directors and select external consultants.

Warrants are granted by the Board of Directors in accordance with authorizations given to it by the shareholders of Ascendis Pharma A/S. As of December 31, 2015, 4,042,312 warrants had been granted, of which 19,580 warrants have been cancelled, 1,292,462 warrants have been exercised, 2,168 warrants have expired without being exercised, and 112,199 warrants have been forfeited. As of December 31, 2015, our board of directors was authorized to grant up to 3,977,092 additional warrants to our employees, board members and select consultants without preemptive subscription rights for the shareholders of Ascendis Pharma A/S. Each warrant carries the right to subscribe for one ordinary share of a nominal value of DKK 1. The exercise price is fixed at the fair market value of our ordinary shares at the time of grant as determined by our board of directors. The exercise prices of outstanding warrants under our warrant programs are approximately €6.48, €8.00, and €15.68 depending on the grant dates. Vested warrants may be exercised in two or four annual exercise periods as described below. Apart from exercise prices and exercise periods, the programs are similar.

Vesting Conditions

Warrants issued during the period from 2008 to 2012 generally vested over 36 months with 1/36 of the warrants vesting per month from the date of grant. However, some of these warrants were subject to shorter vesting periods, to a minimum of 24 months. All such warrants have been exercised or have expired as of December 31, 2015.

Effective from and after December 2012, warrants granted generally vest over 48 months with 1/48 of the warrants vesting per month from the date of grant.

Warrants generally cease to vest from the date of termination in the event that (i) the warrant holder terminates the employment contract and the termination is not a result of breach of the employment terms by us, or (ii) in the event that we terminate the employment contract and the warrant holder has given us good reason to do so. The warrant holder will, however, be entitled to exercise vested warrants in the first exercise period after termination.

Notes to the Consolidated Financial Statements

Warrants issued to consultants, advisors and board members only vest so long as the consultant, advisor or board member continues to provide services to us.

Exercise Periods

Vested warrants may be exercised during certain exercise periods each year. For 1,054,958 outstanding warrants, there are two annual exercise periods that continue for 21 days from and including the day after the publication of (i) the annual report notification—or if such notification is not published—the annual report and (ii) our interim report (six-month report). For these warrants, the last exercise period is 21 days from and including the day after the publication of our interim report for the first half of 2023. For 538,037 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 1,022,908 warrants granted on December 18, 2015, there are four annual exercise periods; each exercise period begins two full trading days after the publication of the public release of our earnings data of a fiscal quarter and continues until the end of the second-to-last trading day in which quarter the relevant earnings release is published. The warrants granted in December 2015 expire ten years after the grant date.

In the event of liquidation, a merger, a demerger or a sale or share exchange of more than 50% of our share capital, the warrantholders may be granted an extraordinary exercise period immediately prior to the transaction in which warrants may be exercised.

Warrants not exercised by the warrant holder during the last exercise period shall become null and void without further notice or compensation or payment of any kind to the warrant holder.

If the warrant holder is a consultant, advisor or board member, the exercise of warrants is conditional upon the warrantholder's continued service to us at the time the warrants are exercised. If the consultant's, advisor's or board member's relationship with us should cease without this being attributable to the warrantholder's actions or omissions, the warrantholder shall be entitled to exercise vested warrants in the pre-defined exercise periods.

Adjustments

Warrantholders are entitled to an adjustment of the number of warrants issued and/or the exercise price applicable in the event of certain corporate changes. Events giving rise to an adjustment include, among other things, increases or decreases to our share capital at a price below or above market value, respectively, the issuance of bonus shares, changes in the nominal value of each share, and payment of dividends in excess of 10% of the Company's equity.

On January 13, 2015, in preparation for the Company's IPO, the shareholders decided at an extraordinary general meeting to issue bonus shares in the ratio of 3:1 of the Company's authorized, issued and outstanding ordinary and preference shares. The decision had a corresponding impact on the number of warrants issued and the exercise prices for outstanding warrants. Accordingly, the number of warrants was adjusted upwards in the ratio of 3:1 with a corresponding downward adjustment of the exercise prices in the ratio of 3:1. As outlined in Note 2, the effect of the bonus shares has been retrospectively reflected in all periods presented in these financial statements.

Notes to the Consolidated Financial Statements

Warrant Activity

The following table specifies the warrant activity during the year:

	Total Warrants	Weighted Average Exercise Price EUR
Outstanding at January 1, 2013	**1,940,412**	**4.89**
Granted during the year	183,888	8.00
Exercised during the year	—	—
Forfeited during the year	—	—
Expired during the year	—	—
Outstanding at December 31, 2013	**2,124,300**	**5.16**
Granted during the year	895,104	7.04
Exercised during the year	—	—
Forfeited during the year	(19,580)	7.91
Expired during the year	—	—
Outstanding at December 31, 2014	**2,999,824**	**5.70**
Granted during the year	1,022,908	15.68
Exercised during the year	(1,292,462)	3.34
Forfeited during the year	(112,199)	7.65
Expired during the year	(2,168)	3.06
Outstanding at December 31, 2015	**2,615,903**	**10.69**
Vested at the balance sheet date	**864,623**	**7.74**

As of December 31, 2015, a total of 2,615,903 warrants were outstanding with a weighted average exercise price of €10.69. 864,623 of these warrants had vested as of December 31, 2015. For comparison, as of December 31, 2014, a total of 2,999,824 warrants were outstanding with a weighted average exercise price of €5.70. 1,710,411 of these warrants had vested as of December 31, 2014 with a weighted average exercise price of €4.47. As of December 31, 2013, a total of 2,124,300 warrants were outstanding with a weighted average exercise price of €5.16. 1,390,968 of these warrants had vested as of December 31, 2013 with a weighted average exercise price of €2.84.

Warrant Compensation Costs

Warrant compensation costs are determined with basis in the grant date fair value of the warrants granted and recognized over the vesting period. Fair value of the warrants is calculated at the grant dates by use of the Black-Scholes Option Pricing model with the following assumptions: (1) an exercise price equal to or above the estimated market price of our shares at the date of grant; (2) an expected lifetime of the warrants determined as a weighted average of the time from grant date to date of becoming exercisable and from grant date to expiry of the warrants; (3) a risk free interest rate equaling the effective interest rate on a Danish government bond with the same lifetime as the warrants; (4) no payment of dividends; and (5) a volatility for comparable companies for a historic period equaling the expected lifetime of the warrants. The expected volatility reflects the assumption that the historical volatility over a period similar to the life of the warrants is indicative of future trends. The expected volatility has been calculated using a simple average of daily historical data of comparable publicly traded companies, as we do not have sufficient data for the volatility of our own share price.

The following table summarizes the input to the Black-Scholes Option Pricing model for warrant grants in 2015, 2014 and 2013:

	2015	2014	2013
Expected volatility	61 — 63%	67 — 68%	63 — 68%
Risk-free interest rate	0.25 — 0.45%	0.15 — 1.32%	0.78 — 1.51%
Expected life of warrants (years)	5.05 — 7.05	4.57 — 6.94	4.92 — 7.43
Weighted average calculated share price	EUR 15.67	EUR 6.48 — 8.00	EUR 3.31 — 7.45
Fair value of warrants granted in the year	EUR 8.02 — 9.45	EUR 6.48 — 7.82	EUR 1.29 — 4.68

Notes to the Consolidated Financial Statements

Warrant compensation cost is recognized in the statement of profit or loss over the vesting period of the warrants granted.

	2015	2014	2013
		(EUR'000)	
Research and development costs	718	327	545
General and administrative expenses	995	947	126
Total warrant compensation costs	**1,713**	**1,274**	**671**

Value of Outstanding Warrants

For the year ended December 31, 2015, the aggregate fair value of outstanding warrants has been calculated at €33.0 million using the Black-Scholes Option Pricing model. The following table specifies the weighted average exercise price and the weighted average life of outstanding warrants:

	Year of Grant	Number of Warrants	Weighted Average Exercise Price EUR	Weighted Average Life (months)
Granted in December	2012	665,188	8.00	91-92
Granted in March, June, September and December	2013	137,349	8.00	91-92
Granted in January, March, June and November	2014	790,458	7.04	92-93
Granted in December	2015	1,022,908	15.68	119-120
Outstanding at December 31, 2015		**2,615,903**	**10.69**	**102-103**
Vested at the balance sheet date		**864,623**	**7.74**	

For the year ended December 31, 2014, a total of 2,999,824 warrants were outstanding with a weighted average exercise price of €5.70 and weighted average life of 53 to 79 months:

	Year of Grant	Number of Warrants	Weighted Average Exercise Price EUR	Weighted Average Life (months)
Granted in September	2008	623,880	2.65	20-21
Granted in March and December	2009	501,596	2.65	20-21
Granted in December	2011	56,168	8.00	20-21
Granted in October and December	2012	756,604	8.00	20-117
Granted in March, June, September and December	2013	166,472	8.00	115-117
Granted in January, March, June and November	2014	895,104	7.04	115-117
Outstanding at December 31, 2014		**2,999,824**	**5.70**	**53-79**
Vested at the balance sheet date		**1,710,411**	**4.47**	

For the year ended December 31, 2013, a total of 2,124,300 warrants were outstanding with a weighted average exercise price of €5.16 and weighted average life of 50 to 60 months:

	Year of Grant	Number of Warrants	Weighted Average Exercise Price EUR	Weighted Average Life (months)
Granted in September	2008	623,880	2.65	20-21
Granted in March and December	2009	501,928	2.65	20-21
Granted in December	2011	58,000	8.00	20-21
Granted in October and December	2012	756,604	8.00	20-117
Granted in March, June, September and December	2013	183,888	8.00	115-117
Outstanding at December 31, 2013		**2,124,300**	**5.16**	**50-60**
Vested at the balance sheet date		**1,390,968**	**2.84**	

Notes to the Consolidated Financial Statements

Note 7—Finance Income and Finance Expenses

	2015	2014	2013
		(EUR'000)	
Interest income	13	—	—
Exchange rate gains	11,035	1,877	158
Total finance income	**11,048**	**1,877**	**158**
Interest expense	(6)	(16)	(8)
Exchange rate losses	(2,791)	(212)	(724)
Total finance expenses	**(2,797)**	**(228)**	**(732)**

Note 8—Tax on Profit/Loss for the Year and Deferred Tax

	2015	2014	2013
		(EUR'000)	
Tax on profit/(loss) for the year:			
Current tax	(652)	(682)	626
Change of deferred tax	—	—	—
	(652)	**(682)**	**626**
Tax for the year can be explained as follows:			
Profit/(loss) before tax	(33,574)	(10,340)	4,705
Tax at the Danish corporation tax rate of 23.5%	**(7,890)**	**(2,533)**	**1,176**
Tax effect of:			
Non-deductible costs	359	378	173
Additional tax deductions	(703)	—	—
Tax credit	787	823	—
Other effects	(330)	483	97
Change in unrecognized deferred tax assets	7,125	167	(820)
Tax on profit/(loss) for the year	**(652)**	**(682)**	**626**
Unrecognized deferred tax asset:			
Tax deductible losses	(13,404)	(5,261)	(2,345)
Deferred income	(725)	(1,835)	(4,367)
Other temporary differences	5	97	(120)
Unrecognized deferred tax asset	**(14,124)**	**(6,999)**	**(6,832)**

The deferred tax assets have not been recognized in the statement of financial position due to uncertainty relating to the future utilization. The deferred tax asset can be carried forward without timing limitations. For tax losses carried forward, certain limitations exist for amounts to be utilized each year.

Under Danish tax legislation, tax losses may be partly refunded by the tax authorities to the extent such tax losses arise from research and development activities. For the year ended December 31, 2015, the jointly taxed Danish entities had a negative taxable income, and accordingly were entitled to a tax refund of approximately €0.8 million, compared to approximately €0.8 million for the year ended December 31, 2014.

Notes to the Consolidated Financial Statements

Note 9—Intangible Assets

	Goodwill (EUR'000)
Cost:	
At January 1, 2014	**3,495**
Additions	—
December 31, 2014	**3,495**
Additions	—
December 31, 2015	**3,495**
Accumulated impairment:	
At January 1, 2014	**—**
Impairment charge	—
At December 31, 2014	**—**
Impairment charge	—
At December 31, 2015	**—**
Carrying amount:	
At December 31, 2015	**3,495**
At December 31, 2014	**3,495**

Goodwill relates to the acquisition of Complex Biosystems GmbH (now Ascendis Pharma GmbH) in 2007. Goodwill was calculated as the excess amount of the purchase price to the fair value of identifiable assets acquired, and liabilities assumed at the acquisition date. Business combinations recognized before January 1, 2012, the Group's date of transition to IFRS, have not been adjusted to IFRS 3, "Business Combinations". Ascendis Pharma GmbH was initially a separate technology platform company, but is now an integral part of our research and development activities, including significant participation in the development services provided to our external collaboration partners. Accordingly, it is not possible to look separately at Ascendis Pharma GmbH when considering the recoverable amount of the goodwill. Goodwill is monitored and tested for impairment on a consolidated level as we are considered to represent one cash-generating unit. The recoverable amount of the cash-generating unit is determined based on an estimation of the Company's fair value less costs of disposal. We have determined the fair value of goodwill after taking into account the market value of our ADSs representing the enterprise value of our group enterprises as of the balance sheet date. The computation of our enterprise value significantly exceeded the carrying amount of our equity, leaving sufficient value to cover the carrying amount of goodwill. With reference to materiality, we have concluded that no further assumptions need to be applied in determining whether goodwill is impaired.

Goodwill is tested for impairment on a yearly 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.

Notes to the Consolidated Financial Statements

Note 10—Property, Plant and Equipment

	Plant and Machinery	Other Equipment	Leasehold Improve-ments	Total
		(EUR'000)		
Cost:				
At January 1, 2014	**2,896**	**737**	**417**	**4,050**
Additions	194	90	121	405
Disposals	—	—	—	—
At December 31, 2014	**3,090**	**827**	**538**	**4,455**
Additions	603	400	36	1,039
Disposals	—	—	—	—
At December 31, 2015	**3,693**	**1,227**	**574**	**5,494**
Accumulated depreciation:				
At January 1, 2014	**(1,566)**	**(404)**	**(107)**	**(2,077)**
Depreciation charge	(334)	(124)	(46)	(504)
Disposals	—	—	—	—
At December 31, 2014	**(1,900)**	**(528)**	**(153)**	**(2,581)**
Depreciation charge	(384)	(118)	(56)	(558)
Disposals	—	—	—	—
December 31, 2015	**(2,284)**	**(646)**	**(209)**	**(3,139)**
Carrying amount:				
At December 31, 2015	**1,409**	**581**	**365**	**2,355**
At December 31, 2014	**1,190**	**299**	**385**	**1,874**

	2015	2014	2013
		(EUR'000)	
Depreciation charges are recognized as:			
Research and development costs	(550)	(500)	(401)
General and administrative expenses	(8)	(4)	(4)
Total depreciation charges	**(558)**	**(504)**	**(405)**

Note 11—Investments in Group Enterprises

Investments in Group enterprises comprise:

Company	Domicile	Ownership
Ascendis Pharma GmbH	Germany	100%
Ascendis Pharma, Inc.	US	100%
Ascendis Pharma, Ophthalmology Division A/S	Denmark	100%
Ascendis Pharma, Endocrinology Division A/S	Denmark	100%
Ascendis Pharma, Osteoarthritis Division A/S	Denmark	100%
Ascendis Pharma, Circulatory Diseases Division A/S	Denmark	100%

Note 12—Share Capital

The share capital of Ascendis Pharma A/S consists of 25,128,242 shares at a nominal value of DKK 1, all in the same share class.

The number of shares of the Company are as follows:

	2015	2014	2013	2012	2011
Changes in share capital					
Beginning of year	16,935,780	10,801,948	10,801,948	10,801,948	10,105,560
Increase through cash contribution	8,192,462	6,133,832	—	—	—
Increase through conversion of debt	—	—	—	—	696,388
End of year	**25,128,242**	**16,935,780**	**10,801,948**	**10,801,948**	**10,801,948**

Notes to the Consolidated Financial Statements

Note 13—Other Reserves

Foreign Currency Translation Reserve

Exchange differences relating to the translation of the results and net assets of our foreign operations from their functional currencies to our presentation currency are recognized directly in other comprehensive income and accumulated in the foreign currency translation reserve.

Share-Based Payment Reserve

Warrants granted under our employee warrant program carry no rights to dividends and no voting rights. The share-based payment reserve represents the fair value of warrants recognized from grant date. Further details of the employee warrant program are provided in Note 6.

	Foreign currency translation reserve	Share-based payment reserve	Total
		(EUR'000)	
At January 1, 2013	**(51)**	**2,105**	**2,054**
Other comprehensive income/(loss) for the year, net of tax	(6)	—	(6)
Share-based payment	—	671	671
December 31, 2013	**(57)**	**2,776**	**2,719**
Other comprehensive income/(loss) for the year, net of tax	(14)	—	(14)
Share-based payment	—	1,274	1,274
At December 31, 2014	**(71)**	**4,050**	**3,979**
Other comprehensive income/(loss) for the year, net of tax	(14)	—	(14)
Share-based payment	—	1,713	1,713
At December 31, 2015	**(85)**	**5,763**	**5,678**

Note 14—Deferred Income

We enter into collaboration agreements which are considered to include multiple elements for revenue recognition purposes. Typically, the collaboration agreements include patent transfers, licenses to our technology platform, development activities and other services related to the development of new products. The elements included in the collaboration agreements typically are inseparable and the payments received from the collaboration partners do not necessarily match the individual deliverables with respect to timing and amount. Accounting for such revenue generating transactions under IAS 18 requires that any consideration received before satisfaction of all criteria for revenue recognition be recognized as deferred income in the balance sheet and recognized as revenue in the consolidated statement of profit or loss as the criteria for revenue recognition are satisfied.

Note 15—Commitments and Contingencies

Operating Leases

We operate from leased premises in Denmark, Germany and the US. In addition, we have entered into operating leases for equipment. The total lease commitment under operating leases was:

	2015	2014
	(EUR'000)	
Within 1 year	971	641
Within 1 to 5 years	1,930	434
After 5 years	767	—
Total commitments held under operating leases	**3,668**	**1,075**

Notes to the Consolidated Financial Statements

Total expenses under operating leases were €904 thousand, €765 thousand and €563 thousand for the financial years ended December 31, 2015, 2014, and 2013, respectively.

Other Purchase Obligations

As of December 31, 2015, we had €2.4 million in committed minimum purchase under agreements with suppliers of goods.

Note 16—Financial Risk Management and Financial Instruments

Capital Management

We manage our capital to ensure that all group entities will be able to continue as going concerns while maximizing the return to shareholders through the optimization of our debt and equity balance. Our overall strategy in this regard has remained unchanged since 2012.

Our capital structure consists only of equity comprising issued capital, reserves and retained earnings. We do not hold any debt.

We are not subject to any externally imposed capital requirements. We review our capital structure on an ongoing basis. As we do not have external debt, such review currently comprises a review of the adequacy of our capital compared to the resources required for carrying out our activities.

Financial Risk Management Objectives

We regularly monitor the access to domestic and international financial markets, manage the financial risks relating to our operations, and analyze exposures to risk, including market risk, such as currency risk and interest rate risk, credit risk and liquidity risk.

We seek to minimize the effects of these risks by managing transactions and holding positions in the various currencies used in our operations. We do not enter into or trade financial instruments for speculative purposes.

Market Risk

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

Foreign Currency Risk Management

We undertake transactions denominated in foreign currencies and, consequently, have exposures to exchange rate fluctuations. Exchange rate exposures are managed through maintaining positions in the various currencies used in our operations and managing payments from the most appropriate positions.

The carrying amounts of our monetary assets and liabilities split on currencies at the end of the reporting period are as follows (EUR equivalents):

	2015	2014
Danish Kroner (DKK)	2,566	1,763
US Dollars (USD)	67,068	47,302
Euro (EUR)	46,558	(427)
British Pounds (GBP)	2,641	(36)
Other	(1,282)	(256)
	117,551	**48,346**

Notes to the Consolidated Financial Statements

Foreign Currency Sensitivity Analysis

We are primarily exposed to US Dollars, or USD, British Pounds, or GBP, and Danish Kroner, or DKK. There is an official target zone of 4.5% between DKK and EUR, which limits the likelihood of significant fluctuations between those two currencies in a short time-frame.

The following table details our sensitivity to a 10% increase and decrease in the EUR against the USD and the GBP, respectively. 10% represents our assessment of the reasonably possible change in foreign currency rates. The sensitivity analysis includes only outstanding foreign currency denominated monetary items and adjusts their translation at the period-end for a 10% change in foreign currency rate. The sensitivity analysis includes external payables and receivables as well as balances held in foreign currencies. A positive number indicates an increase in profit before tax or equity where the USD strengthens 10% against the EUR.

For a 10% weakening of USD against EUR, there would be a comparable negative impact on the profit before tax or equity.

	2015	2014
Profit or loss before tax	6,707	4,730
Equity	6,707	4,730

With respect to GBP, the following table shows the effect of a 10% change in exchange rates against the EUR. A positive number indicates an increase in profit before tax or equity where the GBP strengthens 10% against the EUR. For a 10% weakening of GBP against EUR, there would be a comparable negative impact on the profit before tax or equity.

	2015	2014
Profit or loss before tax	264	(4)
Equity	264	(4)

We believe the sensitivity analysis is representative of the inherent foreign exchange risk associated with our operations.

Interest Rate Risk Management

We are not directly exposed to interest rate risk because our capital structure contains no interest bearing debt. Accordingly, no interest sensitivity analysis has been presented.

Credit Risk Management

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss. We consider all of our material counterparties to be creditworthy. Our exposure to credit risk is continuously monitored, in particular, if agreed payments are delayed.

While the concentration of credit risk is significant, we consider the credit risk for each of our individual customers to be low. Accordingly, we have made no provision for doubtful accounts.

The credit risk on cash and cash equivalents is limited because the counterparties are banks with high credit-ratings assigned by international credit-rating agencies. To spread our credit risk, we deposit our cash reserves with several banks.

Liquidity Risk Management

Ultimate responsibility for liquidity risk management rests with our board of directors. We manage liquidity risk by maintaining adequate reserves and banking facilities by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities.

Notes to the Consolidated Financial Statements

Note 17—Related Party Transactions

Our major shareholders, the Board of Directors and the members of our senior management are considered to be related parties as they can exercise a significant influence on our operations. Related parties also include undertakings in which such individuals have significant interests. Additionally, all our group enterprises are considered related parties.

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.

Apart from equity transactions and remuneration to the Company's Board of Directors and senior management as specified in Note 6, the following transactions took place between the Group and its related parties during the financial year:

	2015	2014	2013
		(EUR'000)	
Board of Directors:			
Purchase of services	0	0	(19)
Total transactions with related parties	**0**	**0**	**(19)**

In February 2015, we completed our initial public offering of ADSs at a price of $18.00 per share, raising $124.2 million before expenses and underwriting commissions. Certain of our existing institutional investors, including investors affiliated with certain of our board members, purchased an aggregate of 1,814,818 ADSs (or approximately $32.7 million) in the offering at the initial public offering price on the same terms as the ADSs sold to the public generally.

The following table sets forth the number of ADSs purchased by our related parties in our initial public offering.

Shareholder	Number of ADSs
Sofinnova Capital V FCPR(1)	185,186
Sofinnova Venture Partners IX, L.P.(2)	222,223
OrbiMed Private Investments V, L.P.	222,223
Entities affiliated with Vivo Capital(3)	185,186

(1) Rafaèle Tordjman, M.D., Ph.D., a member of our board of directors, is a managing partner of Sofinnova Partners.
(2) James I. Healy, M.D., Ph.D., a member of our board of directors, is a general partner of Sofinnova Ventures.
(3) Albert Cha, M.D., Ph.D., a member of our board of directors, is a managing partner of Vivo Capital.

We entered into a registration rights agreement in November 2014 with certain holders of our ordinary shares, including Sofinnova Capital V FCPR, Sofinnova Venture Partners IX, L.P., OrbiMed Private Investments V, L.P. and entities affiliated with Vivo Capital. In December 2015, we entered into an amendment to this registration rights agreement, which provided that such registration rights will also apply to securities held by certain shareholders pursuant to our previously outstanding Preference C shares.

We entered into a registration rights agreement in December 2015 with certain entities affiliated with FMR LLC in connection with their purchase on December 14, 2015 of an aggregate of 1.0 million ADSs representing our ordinary shares. Pursuant to this agreement, we agreed to timely register such shares with the SEC subject to certain conditions.

Notes to the Consolidated Financial Statements

We have entered into indemnification agreements with our board members and members of our senior management.

Except for the information disclosed above, we have not undertaken any significant transactions with members of the Board of Directors, our senior management or the major shareholders, or undertakings in which the identified related parties have significant interests.

Note 18—Ownership

The following persons, or groups of affiliated persons, are known by us to beneficially own more than 5% of our outstanding ordinary shares:

- Sofinnova Capital V FCPR, France
- Gilde Healthcare II Sub-Holding B.V., The Netherlands
- Zweite TechnoStart Ventures Fonds GmbH & Co. KG i.L., Germany
- Sofinnova Venture Partners IX, L.P., USA
- OrbiMed Private Investments V, L.P., USA
- Entities affiliated with Vivo Capital, USA
- Entities affiliated with RA Capital Management, LLC, USA
- Visium Balanced Master Fund, Ltd., Cayman Islands
- Entities affiliated with FMR LLC, USA

The Company's American Depository Shares are held through BNY (Nominees) Limited as nominee, of The Bank of New York Mellon, UK (as registered holder of the Company's outstanding ADSs).

Note 19—Subsequent Events

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

Exhibit 4.4(c)

WARRANT CERTIFICATE
(non-negotiable instrument)

Ascendis Pharma A/S (cvr.no. 2991 8791), with its principal business address at [ADDRESS] (hereinafter referred to as "Ascendis Pharma"), has on [date] issued this Warrant Certificate to

[name]

(hereinafter referred to as the "Warrantholder")

whereby the Warrantholder without payment has received and accepted allocation of [number] warrants, which confer the right to subscribe [number] ordinary shares in Ascendis Pharma at a subscription price of US$ [price] per ordinary share with a nominal value of DKK 1.

The other terms applying to the warrants have been set forth in Ascendis Pharma's articles of association [clause [number] [of appendix [number]], which is attached to this Warrant Certificate.

Hellerup, [date]

Michael Wolff Jensen, Chairman

[Place and date]

[name]

Exhibit 8.1

Ascendis Pharma A/S

Subsidiaries of the Registrant

Name	Jurisdiction of Incorporation
Ascendis Pharma GmbH	Germany
Ascendis Pharma, Inc.	Delaware, USA
Ascendis Pharma, Endocrinology Division A/S	Denmark
Ascendis Pharma, Ophthalmology Division A/S	Denmark
Ascendis Pharma, Osteoarthritis Division A/S	Denmark
Ascendis Pharma, Circulatory Diseases 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: April 15, 2016

By: /s/ Jan Møller Mikkelsen
Name: Jan Møller Mikkelsen
Title: Chief Executive Officer

Exhibit 12.2

Certification by the Principal Financial and Accounting Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Peter Rasmussen, certify that:

1. I have reviewed this annual report on Form 20-F of Ascendis Pharma A/S (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a 15(f) and 15d 15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: April 15, 2016

By: /s/ Peter Rasmussen
Name: Peter Rasmussen
Title: VP Finance and Principal Financial and Accounting Officer

Exhibit 13.1

Certification by the Chief Executive Officer and Principal Financial and Accounting 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, 2015, 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, and Peter Rasmussen, as VP Finance and Principal Financial and Accounting Officer of the Company, each 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; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 15, 2016

By: /s/ Jan Møller Mikkelsen
Name: Jan Møller Mikkelsen
Title: Chief Executive Officer

By: /s/ Peter Rasmussen
Name: Peter Rasmussen
Title: VP Finance and Principal Financial and Accounting Officer