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

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended December 31, 2019

OR

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

For the transition period from _____ to _____

OR

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

Date of event requiring this shell company report

Commission file number: 001-36815

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

The Kingdom of Denmark
(Jurisdiction of incorporation or organization)

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

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

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

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

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

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:

47,985,837 ordinary shares
(as of December 31, 2019)

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

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

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

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

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

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

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

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

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

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

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

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

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

Special Note Regarding Forward-Looking Statements

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

- our expectations regarding a Biologics License Application and Marketing Authorization Application for TransCon Growth Hormone, or TransCon hGH (adopted nonproprietary name lonapegsomatropin);
- our ongoing phase 3 study of TransCon hGH for the treatment of adult growth hormone deficiency, our ongoing phase 2 study of TransCon Parathyroid Hormone, or TransCon PTH, and our ongoing phase 2 study of TransCon C-Type Natriuretic Peptide, or TransCon CNP;
- our pursuit of oncology as our second of three independent therapeutic areas of focus, and our development of a pipeline of product candidates in this therapeutic area;
- our receipt of future milestone or royalty payments from our collaboration partners, and the expected timing of such payments;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- our expectations regarding the potential advantages of our product candidates over existing therapies;
- our ability to enter into new collaborations;
- our expectations with regard to the ability to develop additional product candidates using our TransCon technologies and file Investigational New Drug Applications, or INDs, or equivalents for such product candidates;
- our expectations with regard to the ability to seek expedited regulatory approval pathways for our product candidates, including the potential ability to rely on the parent drug’s clinical and safety data with regard to our product candidates;
- our expectations with regard to our current and future collaboration partners to pursue the development of our product candidates and file INDs or equivalents for such product candidates;
- our development plans with respect to our product candidates;

- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;
- the timing or likelihood of regulatory filings and approvals for our product candidates;
- the commercialization of our product candidates, if approved;
- our commercialization, marketing and manufacturing capabilities of our product candidates and associated devices;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our financial performance; and
- developments and projections relating to our competitors and our industry.

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

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

PART I

Item 1 Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2 Offer Statistics and Expected Timetable

Not applicable.

Item 3 Key Information

A. Selected Financial Data

The selected consolidated financial data as of December 31, 2019 and 2018 and for each of the years ended December 31, 2019, 2018 and 2017 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 as of December 31, 2017 and for the years ended December 31, 2016 and 2015 are derived from the audited consolidated financial statements not appearing in this annual report.

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

	Years Ended December 31,				
(EUR'000, except share and per share data)	**2019**	**2018**	**2017**	**2016**	**2015**
Revenue	13,375	10,581	1,530	4,606	8,118
Research and development costs	(191,621)	(140,281)	(99,589)	(66,022)	(40,528)
General and administrative expenses	(48,473)	(25,057)	(13,482)	(11,504)	(9,415)
Operating profit / (loss)	**(226,719)**	**(154,757)**	**(111,541)**	**(72,920)**	**(41,825)**
Share of profit / (loss) in associate	(8,113)	(321)	—	—	—
Finance income	17,803	24,714	923	7,300	11,048
Finance expenses	(1,221)	(127)	(13,756)	(3,112)	(2,797)
Profit / (loss) before tax	**(218,250)**	**(130,491)**	**(124,374)**	**(68,732)**	**(33,574)**
Tax on profit / (loss) for the year	234	394	477	227	652
Net profit / (loss) for the year	**(218,016)**	**(130,097)**	**(123,897)**	**(68,505)**	**(32,922)**
Other comprehensive income / (loss)					
Items that may be reclassified subsequently to profit or loss:					
Exchange differences on translating foreign operations	(37)	17	65	6	(14)
Other comprehensive income / (loss) for the year, net of tax	**(37)**	**17**	**65**	**6**	**(14)**
Total comprehensive income / (loss) for the year, net of tax	**(218,053)**	**(130,080)**	**(123,832)**	**(68,499)**	**(32,936)**
Profit / (loss) for the year attributable to owners of the Company	(218,016)	(130,097)	(123,897)	(68,505)	(32,922)
Total comprehensive income / (loss) for the year attributable to owners of the Company	(218,053)	(130,080)	(123,832)	(68,499)	(32,936)
	EUR	**EUR**	**EUR**	**EUR**	**EUR**
Basic and diluted earnings / (loss) per share	(4.69)	(3.17)	(3.68)	(2.58)	(1.39)
Number of shares used for calculation (basic and diluted)	46,506,862	41,085,237	33,626,305	26,564,414	23,766,783

The total number of ordinary shares outstanding as of December 31, 2019, 2018, 2017, 2016 and 2015 was 47,985,837, 42,135,448, 36,984,292, 32,421,121 and 25,128,242, respectively. The registered share capital as of December 31, 2019, 2018, 2017, 2016 and 2015 was DKK 47,985,837, DKK 42,135,448, DKK 36,984,292, DKK 32,421,121 and DKK 25,128,242, 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,				
(EUR'000)	**2019**	**2018**	**2017**	**2016**	**2015**
Cash and cash equivalents	598,106	277,862	195,351	180,329	119,649
Total assets	676,732	318,968	210,979	190,071	131,774
Total liabilities	79,618	38,918	23,768	13,458	11,445
Retained earnings / (accumulated deficit)	(611,323)	(393,307)	(263,210)	(139,313)	(70,808)
Total equity	597,114	280,050	187,211	176,613	120,329

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)	**2019**	**2018**	**2017**	**2016**	**2015**
Cash flows from / (used in) operating activities	(175,936)	(138,802)	(95,099)	(60,179)	(43,466)
Cash flows from / used in investing activities	(5,159)	(2,648)	(941)	(672)	(1,039)
Cash flows from / (used in) financing activities	493,593	203,267	124,721	117,462	105,742

Exchange Rate Information

Our business is primarily conducted in the European Union, and we maintain our books and records in euros. We have presented results of operations in euros. In this annual report, financial figures included in or extracted from our consolidated financial statements have been translated in accordance with the guidelines under IFRS. For convenience of the reader, this annual report also includes other translations from euros to U.S. dollars and U.S. dollars to euros. Unless specified as of a specific date, or otherwise indicated, translations from euros to U.S. dollars and from U.S. dollars to euros were made at a rate of €0.890 to $1.00, the official exchange rate quoted by the European Central Bank at the close of business on December 31, 2019. Such U.S. dollar amounts are not necessarily indicative of the actual amounts of U.S. dollars which could have been actually purchased on exchange of euros on the dates indicated.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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

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

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

We are applying our innovative TransCon™ technologies to build a leading, fully integrated biopharmaceutical company and to develop a pipeline of product candidates with potential best-in-class profiles to address unmet medical needs. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused substantially all of our efforts on our research and development

activities and, in particular, developing our lead product candidates, TransCon Growth Hormone, or TransCon hGH, TransCon Parathyroid Hormone, or TransCon PTH, TransCon C-Type Natriuretic Peptide, or TransCon CNP, and our proprietary TransCon technologies. We have only a limited operating history upon which our shareholders and ADS holders can evaluate our business and prospects. Our revenue has been primarily generated through collaboration agreements under which we have received up-front technology licensing fees, payments for the sale of certain intellectual property rights and payments we receive for services rendered to our collaboration partners and other biopharmaceutical companies. Revenue generated from existing or new collaborations may fluctuate significantly over time. Accordingly, going forward, we may incur significant losses from our operations. We had a net loss of €218.0 million during the year ended December 31, 2019 and a net loss of €130.1 million during the year ended December 31, 2018. Our total equity was €597.1 million as of December 31, 2019 compared to €280.1 million as of December 31, 2018. Neither the net loss nor net profit we have experienced in prior years are necessarily indicative of our future results.

None of our product candidates have been approved for commercial sale by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or similar non-U.S. regulatory authorities, and we have not generated revenues from the sale of approved products. We expect that our annual operating expenses may increase over the next several years as we expand our research and development efforts and prepare for commercialization. Even if we receive milestone payments from our current or future collaboration partners or begin receiving revenue from product sales, 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 “Item 3 D. Risks Factors —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. 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;
- our ability to commercialize or co-promote, and/or the ability of our collaboration partners to successfully commercialize, our product candidates;
- developing a sustainable and scalable manufacturing process for any of our approved product candidates and establishing and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate, in amount and quality, products to support clinical development and the market demand for our product candidates, if approved;

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

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

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

Since our inception, most of our resources have been dedicated to our research and development activities and, in particular, developing our proprietary TransCon technologies and our most advanced product candidates. We have funded our operations primarily through issuance of our preference shares, ordinary shares and convertible debt securities and payments to us under our collaboration agreements. For example, in March 2019, we received $ 539.4 million (€480.3 million) in net proceeds from a public offering of American Depositary Shares representing our ordinary shares after deducting the underwriting commissions and offering expenses. As of December 31, 2019, we had cash and cash equivalents of €598.1 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, 2019 will be sufficient to meet our projected cash requirements for at least the 12 months from the date of this annual report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including, but not limited to:

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the achievement of development, regulatory and commercial milestones resulting in the payment to us from our collaboration partners of contractual milestone payments and the timing of receipt of such payments, if any;
- our ability to collect payments which are due to us from our collaboration partners, which in turn is impacted by the financial standing of our collaboration partners;

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

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

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

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

Risks Related to Our Business

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

To date, we have invested a significant amount of our efforts and financial resources in the research and development of our current product candidates utilizing our proprietary TransCon technologies. In particular, we completed a pivotal phase 3 trial for TransCon hGH in pediatric growth hormone deficiency, or GHD, patients in March 2019. In September 2019, we completed the last subject visit forming the two-year follow up for the TransCon hGH phase 3 program in pediatric GHD. In February 2020, we completed enrollment of the trial with 59 subjects and we expect to report top-line data from the one-month blinded portion of the PaTH Forward Trial in mid-April 2020. Following evaluation of Phase 2 data from the PaTH Forward Trial, we expect and plan to initiate a global phase 3 program for TransCon PTH in the fourth quarter of 2020, including trial sites in the United States, Canada, Europe and Asia-Pacific, including Japan. Following successful submission of an IND application in July 2019, we initiated the phase 2 ACcomplisH Trial to evaluate safety and efficacy of TransCon CNP in children (ages 2-10 years) with achondroplasia. Our near-term prospects, including our ability to finance our operations through the receipt of milestone payments and potential up-front licensing payments and generate revenue from product sales, will depend heavily on our successful development and commercialization of our product candidates, if approved. The clinical and commercial success of our product candidates and our TransCon technologies will depend on a number of factors, including the following:

- the outcome and successful execution of our ongoing and planned clinical trials of TransCon hGH, TransCon PTH and TransCon CNP;
- our ability and that of our collaboration partners to establish and maintain commercial-scale manufacturing processes for our product candidates and devices, which has not yet been demonstrated;
- whether our product candidates' safety, tolerability and efficacy profiles will be satisfactory to the EMA, the FDA and similar regulatory authorities to warrant marketing approval;
- whether the EMA, the FDA or similar regulatory authorities require additional clinical trials prior to approval to market our product candidates;
- the prevalence and severity of adverse side effects of our product candidates;
- the occurrence of adverse events that implicate the TransCon technologies, including among any out-licensed product candidates;
- the timely receipt of necessary marketing authorizations for our product candidates and devices from the EMA, the FDA and similar regulatory authorities;
- our ability and that of our collaboration partners to successfully commercialize our product candidates, if approved for marketing and sale by the EMA, the FDA or similar regulatory authorities, including educating physicians and patients about the benefits, administration and use of such products;
- achieving and maintaining compliance with all applicable regulatory requirements;
- acceptance of our product candidates as safe and effective by patients and the medical community;
- acceptance of our devices, including the TransCon hGH auto-injector and the TransCon PTH drug delivery device and associated Bluetooth connectivity features, by patients and the medical community;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- obtaining and sustaining an adequate level of coverage and reimbursement for our product candidates by third-party payors;

- the effectiveness of our and our collaboration partners' marketing, sales and distribution strategies and operations;
- our ability and that of our collaboration partners, or any third-party manufacturer we or our collaborators contract with, to manufacture supplies of our product candidates and to develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practice, or cGMP, requirements;
- enforcing intellectual property rights in and to our product candidates;
- avoiding third-party interference, opposition, derivation or similar proceedings with respect to our patent rights, and avoiding other challenges to our patent rights and patent infringement claims; and
- continued acceptable safety profiles of our product candidates following approval, if approved.

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

Additionally, as part of our clinical and regulatory approval plan for TransCon hGH for pediatric GHD we conducted a phase 3 trial in a pediatric population with a primary endpoint of annualized height velocity measured at 12 months, for which we released top-line results in March 2019, the heiGHt Trial, and a separate safety study, the fliGHt (switch) Trial, which was designed to evaluate TransCon hGH in subjects who are primarily treatment experienced with daily GH, although a subgroup of younger subjects may be treatment-naïve. In September 2019, we completed the last subject visit forming the two-year follow up for the TransCon hGH phase 3 program in pediatric GHD. Nearly all subjects who completed either the heiGHt or fliGHt Trials have enrolled in an open-label extension study, the enliGHten Trial, which is designed to provide long-term safety data in approximately 300 patients to support the potential future regulatory filings for TransCon hGH. If we have to, or chose to, conduct additional trials to support regulatory approval of TransCon hGH in the United States, the European Union or other jurisdictions, this could increase the amount of time and expense required for regulatory approval of TransCon hGH in the United States or other jurisdictions, if approved at all.

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

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

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

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

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

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

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

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

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

the EEA or of a New Drug Application, or NDA, or Biologics License Application, or BLA, approval in the United States. As a result, the EMA or the FDA may not accept data from clinical trials conducted outside the EEA or the United States, respectively, and may require that we conduct additional clinical trials or obtain additional data before we can submit an NDA or BLA in the United States or a marketing authorization application in the EEA. The EMA or the FDA may even require conducting additional clinical trials in the EEA or the United States, respectively.

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

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

We rely on our collaboration partners to conduct certain clinical studies. For example, in November 2018, we announced the formation of VISEN Pharmaceuticals, or Visen, a company established to develop, manufacture, and commercialize our endocrinology rare disease therapies in Greater China. In connection with the formation of Visen, we granted Visen exclusive rights to develop and commercialize our rare disease endocrinology products based on our proprietary TransCon technologies, including TransCon hGH, TransCon PTH and TransCon CNP, in Greater China for use in all human indications, subject to certain exceptions. We may also enter into collaboration agreements with other parties in the future relating to our other product candidates. Under our existing collaboration agreements, our collaboration partners are responsible for completing preclinical and/or clinical development and obtaining and maintaining regulatory approval for the applicable product candidates from the EMA, the FDA, the National Medical Product Administrations of the People’s Republic of China, or NMPA, and similar regulatory authorities. Ultimately, if such product candidates are advanced through clinical trials and receive marketing approval from the EMA, the FDA, the NMPA or similar regulatory authorities, such partners will be responsible for commercialization of these collaboration products. The potential for us to obtain future development milestone payments and, ultimately, generate revenue from royalties on sales of such collaboration products depends entirely on successful development, regulatory approval, marketing and commercialization by our collaboration partners.

If our collaboration partners do not perform in the manner we expect or fulfill their responsibilities in a timely manner, or at all, if our agreements with them terminate or if the quality or accuracy of the clinical data they obtain is compromised, the clinical development, regulatory approval and commercialization efforts related to our collaboration product candidates could be delayed or terminated and it could become necessary for us to assume the responsibility at our own expense for the clinical development of such product candidates. In that event, we would likely be required to limit the size and scope of efforts for the development and commercialization of such product candidate, to seek additional financing to fund further development, or to identify alternative collaboration partners, and our potential to generate future revenue from royalties and milestone payments from such product candidate would be significantly reduced or delayed and our business would be harmed. Our existing collaborations and any future collaboration arrangements that we may enter into with third parties may not be scientifically or commercially successful. In addition to the risks inherent in the development of a drug product candidate, factors that may affect the success of our collaborations include the following:

- our collaboration partners have the unilateral ability to choose not to develop a collaboration product for one or more indications for which such product has been or is currently being evaluated, and our collaboration partners may choose to pursue an indication that is not in our strategic best interest or to forego an indication that they believe does not provide significant market potential even if clinical data is supportive of further development for such indication;

- our collaboration partners may choose not to develop and commercialize our collaboration products in certain relevant markets;
- our collaboration partners may take considerably more time advancing our product candidates through the clinical and regulatory process than we currently anticipate, which could materially delay the achievement of milestones and, consequently the receipt of milestone payments from our collaboration partners;
- our collaboration partners have substantial discretion under their respective agreements regarding how they structure their efforts and allocate resources to fulfill their obligations to diligently develop, obtain regulatory approval for and commercialize our collaboration products;
- our collaboration partners control all aspects of commercialization efforts under their respective license agreements and may change the focus of their development and commercialization efforts or pursue higher-priority programs and, accordingly, reduce the efforts and resources allocated to their collaborations with us;
- our collaboration partners are solely responsible for obtaining and maintaining all regulatory approvals and we or our collaboration partners may fail to develop a commercially viable formulation or manufacturing process for our product candidates, and we or our collaboration partners may fail to manufacture or supply sufficient drug substance for commercial use, if approved, which could result in lost revenue under such collaborations;
- our collaboration partners may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- if any of our agreements with our collaboration partners terminate, we will no longer have any rights to receive potential revenue under such agreement, in which case we would need to identify alternative means to continue the development, manufacture and commercialization of the affected product candidates, alone or with others;
- our collaboration partners have the discretion to sublicense their rights with respect to our collaboration technology in connection with collaboration product candidates to one or more third parties without our consent;
- our collaboration partners may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive with products on which they are collaborating with us or which could affect our collaboration partners' commitment to the collaboration; and
- if our collaboration partners receive approval for any of the collaboration product candidates, reductions in marketing or sales efforts or a discontinuation of marketing or sales of our product candidates by our collaboration partners would reduce any royalties we could be entitled to receive, which are based on the sales of our product candidates by our collaboration partners.

In addition, the collaboration agreements provide our collaboration partners with rights to terminate such agreements and licenses under various conditions, which if exercised would adversely affect our product development efforts, make it difficult for us to attract new partners and adversely affect our reputation in the business and financial communities. Our collaboration partners have the right to terminate their respective collaboration agreements with us, upon advance written notice, in the event of our uncured material breach of the agreement and for convenience. In addition, Visen may terminate in the event of our bankruptcy or insolvency.

The timing and amount of any milestone and royalty payments we may receive under our agreements with our collaboration partners and the value of any equity we own in our collaboration partners (such as the equity we own in Visen) will depend on, among other things, the efforts, allocation of resources, and successful development and commercialization of our product candidates by our collaboration partners. We cannot be certain that any 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 also cannot be certain that any equity we own in our collaboration partners (such as the equity we own in Visen) will maintain its value or grow in value.

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

We may form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to our independent programs that we believe will complement or augment our existing business. We have historically engaged, and intend to continue to engage, in partnering discussions with a range of biopharmaceutical companies and could enter into new collaborations at any time. For example, in November 2018, we announced the formation of Visen, a company established to develop, manufacture, and commercialize our endocrinology rare disease therapies in Greater China. In connection with the formation of Visen, we granted Visen exclusive rights to develop and commercialize our rare disease endocrinology products based on our proprietary TransCon technologies, including TransCon hGH, TransCon PTH and TransCon CNP, in Greater China for use in all human indications, subject to certain exceptions. We face significant competition in seeking appropriate strategic partners, and the negotiation process to secure appropriate terms is time-consuming and complex. Any delays in identifying suitable development partners and entering into agreements to develop our product candidates could also delay the commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. Moreover, we may not be successful in our efforts to establish such a strategic partnership for any future product candidates and programs on terms that are acceptable to us, or at all. This may be for a number of reasons. For example, under our collaboration with Visen, Visen has a right of first negotiation to develop certain of our endocrinology product candidates in Greater China, so our ability to negotiate such a collaboration with suitable third parties may be hampered by such rights we granted to Visen. Additionally, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, and/or third parties may not view our product candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile. Even if we are successful in entering into a strategic alliance or license arrangement, there is no guarantee that the collaboration will be successful, or that any future collaboration partner will commit sufficient resources to the development, regulatory approval, and commercialization of our product candidates, or that such alliances will result in us achieving revenues that justify such transactions.

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

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

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

to yield product candidates for clinical development or commercialization for many reasons, including the following:

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

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

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

From time to time, we may publish interim or preliminary data from our clinical studies. For example, in January 2020, we announced preliminary data from our phase 2 study of TransCon PTH. 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.

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

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

We do not currently have the ability to independently conduct clinical trials or nonclinical studies. We rely on medical institutions, clinical investigators, contract laboratories, collaboration partners and other third parties, such as CROs, to conduct clinical trials of our product candidates. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we control only certain aspects of their activities and have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our nonclinical studies and our clinical trials, we remain responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good laboratory practices, or GLPs, for nonclinical studies, and good clinical practices, or GCPs, for clinical studies. GLPs and GCPs are regulations and guidelines enforced by the Competent Authorities of the Member States of the European Economic Area, or EEA, the FDA and comparable foreign regulatory authorities for all of our products in nonclinical and clinical development, respectively. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third party contractors fail to comply with applicable regulatory requirements, including GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the EMA, the FDA, or similar regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be certain that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations. The failure of our contract manufacturers to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

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

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

- the quality of our relationships with patient advocacy groups; and
- coverage and reimbursement policies of government and other third-party payors.
- If our product candidates that obtain regulatory approval do not achieve significant market acceptance or commercial success, this could harm our business, results of operations and prospects, and the value of our shares or ADSs.

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

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

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

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

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

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

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

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

We are aware of several pharmaceutical and biopharmaceutical companies that have commenced clinical studies of products or have successfully commercialized products addressing areas that we are targeting. While there are currently no long-acting growth hormone treatment options available in the United States or Europe, a permanently PEGylated long-acting growth hormone developed by GeneScience Pharmaceuticals Co., Ltd. is available in China and the Somatropin Biopartners product (LB03002), is available in Korea. In addition to the currently approved and marketed daily growth hormone therapies, there are a variety of experimental growth hormone therapies based on permanent modification in different stages of clinical development by various companies, including GeneScience Pharmaceuticals Co., Ltd., Genexine Inc, JCR Pharmaceuticals Co., Ltd., Novo Nordisk A/S, and OPKO Health, Inc. (in collaboration with Pfizer Inc.). In addition, Shire plc owns the rights to NATPARA, a treatment for hypoparathyroidism. NATPARA was voluntarily recalled in September 2019 in the U.S. and is now only available to a limited number of seriously-ill patients through a Special Use Program offered by its manufacturer, Takeda Pharmaceutical Company. In addition, we are aware of several academic groups and companies working on making longer acting agonists of the PTH receptor, or PTH1R. Other companies and groups are developing or commercializing therapies for hypoparathyroidism, including Shire, Chugai Pharmaceutical Co., Ltd., Entera Bio, Extend Biosciences, Massachusetts General Hospital, Alizé Pharma, Bridgebio and Eli Lilly and Company. BioMarin Pharmaceutical, Inc. is developing vosoritide for the treatment of achondroplasia, and other companies that are developing therapies for achondroplasia include Pfizer, QED Therapeutics and BioClin Therapeutics, Inc. In addition to product based competition, our TransCon technologies face technology based competition as we believe other companies are developing or evaluating enhanced drug delivery and sustained release technologies. In particular, we believe Nektar Therapeutics, OPKO Health, Inc., ProLynx LLC and Serina Therapeutics, Inc. are developing technologies that use reversible linkers and that may be competitive with our TransCon technologies.

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

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

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

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

Many of our competitors have:

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

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

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

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

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

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

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

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

We apply our TransCon technologies to both approved and unapproved parent drugs to extend the life of such drugs in the body, and to enhance the overall benefit of a given therapy. Even when applied to approved parent drugs, we have generated limited clinical data on our product candidates using our systemic TransCon technologies with respect to safety and efficacy for long-term treatment in humans. The long-term safety and efficacy of our TransCon

technologies and the extended life in the body of our product candidates utilizing TransCon technologies compared to currently approved products is unknown, and it is possible that our product candidates may have an increased risk of unforeseen reactions following extended treatment relative to other currently approved products. If extended treatment with product candidates utilizing TransCon in our ongoing or future clinical trials results in any concerns about the safety or efficacy of our TransCon technologies, we may be unable to successfully develop or commercialize our product candidates.

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

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

We have limited clinical data on product candidates utilizing the TransCon technology 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 systemic TransCon technologies to indicate whether they are safe or effective for long-term use in humans, including the safety of any degradation products that may result after the TransCon carrier and TransCon linker are cleaved from the parent drug molecule. As an example, our TransCon prodrugs utilize polyethylene glycol, or PEG, and hydrogels incorporating PEG-based polymers as TransCon carriers. Although the safety and efficacy of PEG and permanently PEGylated proteins has been demonstrated within their respective indications by the approval of drugs such as PegIntron®, PegaSys®, Neulasta®, Somavert®, Cimzia®, Krystexxa®, Adynovate® and Rebinyn® and we are not aware of any evidence for PEG-related safety issues with PEGylated proteins in the clinic, health authorities, including the EMA, have historically posed general questions relating to the distribution, elimination, and the potential for PEG accumulation to pharmaceutical companies involved in the development of PEGylated drug products. If treatment with any of our product candidates in our clinical trials results in concerns about their safety or efficacy, we and our collaboration partners may be unable to successfully develop or commercialize any or all of our TransCon technologies based product candidates or enter into collaborations with respect to our product candidates.

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

We have generated limited clinical data on TransCon PTH and TransCon CNP. It is unknown whether long-term repeated administration of TransCon PTH or TransCon CNP could result in issues that may adversely affect safety. In addition, we have generated no clinical data on our preclinical product candidates. If extended treatment with TransCon PTH, TransCon CNP, or any of our preclinical product candidates, in our clinical trials, results in any safety or efficacy concerns, we may be unable to successfully develop or commercialize our product candidates or enter into collaborations with respect to our product candidates.

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

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

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

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

Any biological product for which we intend to seek approval may face competition sooner than anticipated.

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty, and any processes adopted by the FDA to implement the BPCIA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our future biological product candidates approved under a BLA should qualify for the twelve-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other

aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

We have limited direct sales and distribution capabilities and no sales experience with any of our own product candidates and we may not be able to successfully commercialize any of our product candidates.

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

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

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

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

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

In addition, if our product candidates are approved, to produce the quantities necessary to meet anticipated market demand, we and/or our collaboration partners will need to secure sufficient manufacturing capacity with third-party manufacturers. If we and/or our collaboration partners are unable to produce our product candidates in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, our revenues and gross margins could be adversely affected. For example, public health epidemics or pandemics, such as the novel coronavirus disease (COVID-19) currently impacting multiple jurisdictions worldwide may impact the ability of our existing or future manufacturers to perform their obligations under our manufacturing agreements with such parties. Such failure or substantial delay could materially harm our business. To be successful, our product candidates must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. We and/or 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 collaboration with Visen, we are obligated to use commercially reasonable efforts to supply clinical trial material for Visen to conduct clinical trials therefor, and will negotiate in good faith with Visen the terms and conditions governing our commercial supply of relevant products to Visen. In turn, we currently rely on third party manufacturers in fulfilling our supply obligations to Visen. For additional information regarding the risks of our dependence on our collaboration partners, see the risk factors above “Item 3 D. Risk Factors—We are substantially dependent on the success of our product candidates, which may not be successful in nonclinical studies or clinical trials, receive regulatory approval or be successfully commercialized” and “Item 3 D. Risk Factors—We depend on collaboration partners to develop and conduct clinical studies with, obtain regulatory approvals for, and market and sell our collaboration product candidates, and if such collaboration partners fail to perform as expected, or are unable to obtain the required regulatory approvals for such product candidates, the potential for us to generate future revenue from such product candidates would be significantly reduced and our business would be significantly harmed.”

If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or similar regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, the Competent Authorities of the Member States of the EEA, or a similar regulatory authority does not

approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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

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

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

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

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

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

It is generally necessary for us to secure certain levels of insurance as a condition for the conduct of clinical studies. We believe that our product liability insurance for clinical studies is sufficient to cover claims. We currently maintain liability insurance with certain specified coverage limits. We cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop. We currently carry product liability insurance covering use in our clinical trials in the amount of $20 million in the aggregate on our primary insurance policy and $40 million in the aggregate on our excess insurance policy. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various, limits, exclusions and deductibles, and given these various limits, exclusions and deductibles, we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms.

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

As of December 31, 2019, we had 330 full-time employees worldwide, with key facilities in Denmark, Germany, and the United States. As we and/or our collaboration partners advance our product candidates through the development and commercialization process, we will need to expand managerial, operational, financial and other resources to manage our operations, preclinical and clinical trials, research and development activities, regulatory filings, manufacturing and supply activities, and any marketing and commercialization activities or contract with other organizations to provide these capabilities for us. As operations expand, we expect that we will need to manage additional relationships with various collaboration partners, suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures across a global organization. Such growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we either internally, together with our collaboration partners or through third party contractors, as applicable:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Due to the international scope of our operations, fluctuations in exchange rates, particularly between the euro, the Danish krone and the U.S. dollar, may adversely affect us. Although we are based in Denmark, we source research and development, manufacturing, consulting and other services from several countries. In addition, our arrangements with our collaboration partners are denominated in euros and U.S. dollars. Further, potential future revenue may be derived from abroad, including from the United States. We currently attempt to limit our exposure to exchange rate risks by maintaining cash positions in the currencies in which we expect to incur the majority of our future expenses; however, for a variety of reasons we may be unable to maintain cash positions in the currencies in which we expect to incur the majority of our future expenses and we may fail to predict the currency of our future

expenses, accurately or at all. As a result, our business and the price of the ADSs may be affected by fluctuations in foreign exchange rates between the euro and these other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period. We currently do not enter into foreign exchange contracts to cover our exposure to exchange rate fluctuations, or any other form of exchange rate hedging arrangements. If we fail to manage foreign exchange risk adequately our business, results of operations and prospects, and the value of our shares or ADSs may be adversely affected.

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

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

Following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdrew from the European Union on January 31, 2020 and entered into a transition period during which it will continue its ongoing and complex negotiations with the European Union relating to the future trading relationship between the parties. Significant political and economic uncertainty remains about whether the terms of the relationship will differ materially from the terms before withdrawal, as well as about the possibility that a so-called "no deal" separation will occur if negotiations are not completed by the end of the transition period. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of the ADSs.

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

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

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

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

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

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

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

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

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

- the research methodology used may not be successful in identifying potential product candidates; or

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

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

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

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

In particular, we are highly dependent upon Jan Møller Mikkelsen, our President and Chief Executive Officer. The loss of services of this individual could result in delays in product development and harm our business.

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

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

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

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

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures, and public health epidemics or pandemics, such as the novel coronavirus disease (COVID-19) currently impacting multiple jurisdictions worldwide. 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.

The global pandemic caused by COVID-19 could materially adversely impact our business, including our clinical trials.

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

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- significant increases in expenses required to manage impacts to our business to complete our planned operations within our projected timelines;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as comparator drugs used in certain of our clinical trials;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of regulatory authorities to accept data from clinical trials in these affected geographies.

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

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

Risks Related to Government Regulatory and Legal Requirements

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

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

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

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

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

The time required to obtain approval by the EMA, the FDA and comparable authorities is unpredictable, typically takes many years following the commencement of clinical studies, and depends upon numerous factors. The EMA, the FDA and comparable authorities have substantial discretion in the approval process and we may encounter

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

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

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

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

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

We have not yet received any regulatory approvals required for the commercial sale of TransCon hGH, TransCon PTH, TransCon CNP, or any of our other product candidates in the United States, the EMA or in any other jurisdiction. Furthermore, we have yet to submit an NDA or BLA to the FDA, or a Marketing Authorization Application, or MAA, to the EMA, national regulatory authorities in Europe or to any international regulatory authorities for any of our product candidates. We have only limited experience in filing and pursuing applications

necessary to obtain regulatory approval or licensure, and we cannot be certain that any of our product candidates will be approved or licensed for marketing. The process of applying for regulatory approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the product candidates involved. If any or all of our product candidates are not approved, this could harm our business, results of operations and prospects, and the value of our shares or ADSs.

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

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

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

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

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

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

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

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

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

Pharmaceutical products, including product candidates employing our TransCon technologies, are subject to extensive and rigorous government regulation. The FDA, the EMA and other regulatory authorities regulate the development, testing, manufacture, safety, efficacy, record- keeping, labeling, storage, approval, advertising,

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

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

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

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

- delays;
- warning letters;
- fines;
- importation restrictions;
- product recalls or seizures;
- injunctions;
- refusal of the FDA, EMA or other regulatory authorities to review pending market approval applications or supplements to approval applications;
- total or partial suspension of production;

- suspension or debarment from selling FDA-regulated products to the U.S. government for periods of time that vary depending on the cause of such suspension or debarment;
- civil penalties;
- withdrawal or revocation of previously approved marketing applications or licenses; and
- criminal prosecutions.

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

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

In the United States, advertising and promotional materials must comply with FDA rules in addition to other potentially applicable U.S. laws. In particular, the promotional claims that we would be permitted to make for our products would be limited to those supported by (or, under FDA guidance, consistent with) the approved product labeling. In addition, under the Federal Food, Drug, and Cosmetic Act, particular restrictions are placed on the distribution of human growth hormone products, potentially including TransCon hGH. The distribution of product samples to physicians must also comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the FDA's cGMP requirements. Application holders must obtain FDA approval for many product and manufacturing changes, depending on the nature of the change. Sales, marketing, and scientific/educational grant programs must comply with the U.S. Anti-Kickback Statute, the False Claims Act, as amended, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Certain payments and other transfers of value to U.S. licensed physicians (as defined under statute) and teaching hospitals must be reported under the Physician Payments Sunshine Act. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to U.S. consumer protection and unfair competition laws.

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

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

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

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

In addition, the FDA's policies may change and additional government laws or regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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, off-label promotion of medicinal products is not permitted. Furthermore, advertising to the general public of medicinal products which are available on medical prescription only is prohibited. The requirements are regulated by both E.U. regulations (such as advertising of medicinal products and reporting of adverse events) as well as national applicable regulations (namely related to prices and promotional activities).

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

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

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

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

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

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

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

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

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates, if approved, and on related parent drugs. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Many countries, including the European Union member states, established complex and lengthy procedures to obtain price approvals, coverage and reimbursement. These procedures vary from country to country but are commonly initiated after grant of the related marketing authorization. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the

reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. As an example, many EU member states review periodically their decisions concerning the pricing and reimbursement of medicinal products. The outcome of these reviews cannot be predicted and could have adverse effects on the pricing and reimbursement of our medicinal products in the EU member states.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

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

In the EEA, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the E.U. Community and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the medicinal product. An E.U. orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. We have as of December 31, 2019 received orphan drug designation for TransCon hGH in the European Union and for TransCon PTH and TransCon CNP in the United States.

In the EEA, marketing authorization applications for new medicinal products not authorized in the EU will only be regarded as valid, if they include one of the following: (i) the results of all studies performed and details of all information collected in compliance with a paediatric investigation plan; PIP, agreed with the EMA's Pediatric

Committee, or the PDCO, (ii) a decision of the EMA granting a waiver from the obligation to provide the results of studies in the paediatric population in accordance with a PIP, or (iii) a decision by the EMA agreeing to a deferral of the initiation or completion of some or all of the measures set out in the PIP. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the European Union and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension. For orphan-designated medicinal products, the 10-year period of market exclusivity is extended to 12 years. At this time, although other long-acting products in development have received PIP waivers, we are currently in discussions with PDCO and have not agreed to a PIP or received a PIP waiver for TransCon hGH.

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

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

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

- the U.S. Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under U.S. federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;
- U.S. false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- U.S. federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the U.S. Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the U.S. federal physician sunshine requirements under the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers beginning in 2022, and teaching hospitals, and ownership and investment interests held by physicians (as defined under statute) and their immediate family members;
- state law equivalents of each of the above U.S. federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;
- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information;
- 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. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, effective January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context; and
- European and other foreign law equivalents of each of the laws, including regulation regarding advertising of medicinal products and reporting requirements detailing interactions with and payments to healthcare providers.

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

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

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

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

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

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

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

From time to time, legislation is drafted and introduced in U.S. Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. In addition, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be interpreted and implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions

impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

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

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

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

We expect that the current presidential administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. For example, the Tax Cuts and Jobs Act, enacted on December 22, 2017, removes penalties for not complying with the ACA's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that because the individual mandate is a critical and inseverable feature of the ACA, the remaining provisions of the ACA were invalid as well. Upon appeal, the U.S. Court of Appeals for the Fifth Circuit affirmed that the individual mandate was unconstitutional but remanded the case back to the U.S. District Court to determine what portions of the ACA, if any, might continue to be valid. On January 21, 2020, the U.S. Supreme Court declined a motion by the U.S. House of Representatives and others seeking expedited review of the case. It is unclear how these decisions, subsequent appeals and other efforts to challenge, repeal or replace the ACA will impact the law. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted, including reductions in Medicare payments to providers, capped at 2% per fiscal year, which went into effect on April 1, 2013. These reductions, extended by subsequent legislation will stay in effect through 2029 unless additional Congressional action is taken, further reductions to Medicare payments to several types of providers, including hospitals, and an increased statute of limitations period for the government to recover overpayments to providers from three to five years. Recently, there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Individual states in the United States have also become increasingly

active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including through constraints on reimbursement, imposition of mandatory discounts, discounts, restrictions on access to certain products, transparency measures, and programs for importation from other countries or bulk purchasing.

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

Risks Related to Our Intellectual Property

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

Our success depends in part on our ability to:

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

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

As of December 31, 2019, twenty-four patents have been issued to us in the United States. 16 patents are directed to our TransCon technologies and five are directed to TransCon hGH. In addition, as of December 31, 2019, we have approximately 139 issued patents in jurisdictions outside of the United States, at least 74 of which are directed to our TransCon technologies, and 35 of which are directed to our product candidates. As of December 31, 2019, our TransCon hGH is covered by seven different patent families and an additional nine patent families covering the auto-injector device, our TransCon PTH is covered by seven different patent families and our TransCon CNP is covered by 11 different patent families. Most members of these families are applications in an early stage, so it is impossible to make any statements regarding whether or not they will be granted. We are not aware of any challenge to our issued patents, in the United States, Europe or in any other jurisdiction.

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

rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may harm our business.

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

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

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or our in-licensed issued patents may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- any patents we obtain or our in-licensed issued patents may not be valid or enforceable; or
- we may not develop additional proprietary technologies that are patentable.

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

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering the product candidate, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during

prosecution. The outcomes of proceedings involving assertions of invalidity and unenforceability are unpredictable. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which would render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of, but that we do not believe are relevant to our current or future patents, that could nevertheless be determined to render our patents invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability of our patents covering one of our product candidates, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would harm our business. Moreover, our competitors could counterclaim in any suit to enforce our patents that we infringe their intellectual property. Furthermore, some of our competitors have substantially greater intellectual property portfolios, and resources, than we do.

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

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

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

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

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

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

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

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

Litigation may be necessary to:

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

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

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

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

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

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

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

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

As of December 31, 2019, 80 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.

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Ordinary Shares and ADSs

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

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

- results from, or any delays in, clinical trial programs relating to our product candidates, including clinical trials for TransCon hGH, TransCon PTH and TransCon CNP;
- our ability to apply our TransCon technologies to therapeutic areas other than endocrinology, including the therapeutic area of oncology;
- our ability to commercialize or obtain regulatory approval for our product candidates, or delays in commercializing or obtaining regulatory approval;
- announcements of regulatory approval or a complete response letter to our product candidates, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements relating to current or future collaborations or joint ventures, including decisions regarding the exercise by our collaboration partners of their options, if any, or any termination by them of their collaborations with us;
- timing and amount of payments to us under our collaborations or joint ventures, if any;
- announcements of therapeutic innovations or new products by us or our competitors;

- announcements regarding the parent drugs that we use in developing our product candidates;
- adverse actions taken by regulatory authorities with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our product candidates;
- any adverse changes to our relationship with any manufacturers or suppliers;
- the success of our testing and clinical trials;
- the success of our efforts to acquire, license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- European Medicines Agency, or EMA, FDA or other similar regulatory actions affecting us or our industry or other healthcare reform measures in the European Union, United States or in other markets;
- changes in the structure of healthcare payment systems;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of the ADSs;
- sales of ordinary shares and/or ADSs by us, our senior management and board members, holders of the ADSs or our shareholders in the future;
- general economic and market conditions and overall fluctuations in the United States and international equity markets; and
- the loss of any of our key scientific or senior management personnel.

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

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

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

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

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

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

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

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

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

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

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

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

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

If our existing shareholders or holders of ADSs sell, or indicate an intention to sell, substantial amounts of our ordinary shares or ADSs in the public market, the trading price of our ADSs could decline. Based upon the number of shares outstanding as of March 1, 2020, we have outstanding a total of 47,985,837 ordinary shares. Of those shares, approximately 6,776,094 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, we registered for resale by shares owned by certain selling shareholders, including shareholders that are affiliated with members of our board of directors.

As of December 31, 2019, there were 5,820,211 warrants outstanding. If these warrants are exercised an additional 5,820,211 ordinary shares or ADSs will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional ordinary shares or ADSs are sold, or if it is perceived that they will be sold, in the public market, the trading price of the ADSs could decline. Any sales of securities by these security holders could have a negative effect on the trading price of the ADSs.

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

As of March 1, 2020, our senior management, board members, holders of 5% or more of our share capital and their respective affiliates beneficially own approximately 60.5% of our outstanding voting securities. As a result, these security holders have the ability either alone or voting together as a group to determine and/or significantly influence the outcome of matters submitted to our shareholders for approval, including the election and removal of board members, payment of dividends, amendments to our articles of association, including changes to our share capital or any mergers, demergers, liquidations and similar transactions. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares or ADSs that our shareholders or ADS holders may feel are in their best interest as a shareholder or holder of ADSs. In addition, this group of shareholders may have the ability to control our management and affairs. Such control and concentration of ownership may affect the market price of the ADSs and may discourage certain types of transactions, including those involving actual or potential change of control of us (whether through merger, consolidation, take-over or other business combination), which might otherwise have a positive effect on the market price of the ADSs.

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

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

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

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

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

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

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

We report under the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act and although we are subject to Danish laws and regulations with regard to such matters and intend to furnish quarterly financial information to the SEC, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each fiscal year, while U.S. domestic issuers that are large accelerated filers are required to file their annual report on Form 10-K within 60 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, our shareholders and the holders of our ADS may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

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

We have adopted and presented our consolidated financial statements in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board. IFRS is an internationally recognized body of accounting principles that are used by many companies outside of the United States to prepare their financial statements; and the SEC permits foreign private issuers such as our company to prepare and file their financial statements in accordance with IFRS rather than U.S. GAAP. IFRS accounting principles are different from

those of U.S. GAAP, and SEC rules do not require us to provide a reconciliation of IFRS accounting principles to those of U.S. GAAP. Investors who are not familiar with IFRS may misunderstand certain information presented in our consolidated financial statements. Accordingly, we suggest that readers of our consolidated financial statements familiarize themselves with the provisions of IFRS accounting principles to better understand the differences between these two sets of principles.

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

We qualify as a foreign private issuer. As a result, in accordance with the listing requirements of the Nasdaq Global Select Market, we rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of the Nasdaq Global Select Market. For instance, the Listing Rules for the Nasdaq Stock Market, or the Nasdaq Listing Rules, for domestic U.S. issuers require listed companies to have, among other things, a majority of their board members be independent, and to have independent director oversight of executive compensation, nomination of board members and corporate governance matters. As a foreign private issuer, however, while we intend to comply with these requirements, we are permitted to follow home country practice in lieu of the above requirements. Danish law does not require that a majority of our board consist of independent directors or the implementation of a remuneration committee or nominating and corporate governance committee, and our board may thus in the future not include, or include fewer, independent directors than would be required if we were subject to the Nasdaq Listing Rules, or they may decide that it is in our interest not to have a remuneration committee or nominating and corporate governance committee, or have such committees governed by practices that would not comply with 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, 2020, 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, 2021. To maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares or ADSs must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must not be administered principally inside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status

would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

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

Under the Internal Revenue Code of 1986, as amended, the determination of passive foreign investment company, or PFIC, status is fact-specific, and generally cannot be made until after the close of the taxable year in question. Based on the market price of our ADSs, the value of our assets and the composition of our income and assets, we do not believe we were a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2019. However, we cannot assure you we will not be a PFIC for any taxable year.

A non-U.S. corporation will be considered a PFIC for any taxable year if either (1) at least 75% of its gross income for such year is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during such year) is attributable to assets that produce or are held for the production of passive income. A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). If we are a PFIC for any taxable year during which a U.S. Holder (as defined in "Item 10 E. Additional Information—Taxation—Material U.S. Federal Income Tax Consequences to U.S. Holders") holds ordinary shares or ADSs, the U.S. Holder may be subject to adverse tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of an interest charge with respect to such gain and certain dividends and (iii) compliance with certain reporting requirements. Each U.S. Holder is strongly urged to consult its tax advisor regarding these issues. See "Item 10 E. Additional Information—Taxation—Material U.S. Federal Income Tax Consequences to U.S. Holders."

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

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

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

We do not currently intend to pay any cash dividends on our ordinary shares for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, our shareholders and ADS holders are not likely to receive any dividends on their investment for the foreseeable future. Because we do not intend to pay

dividends, our shareholders' and ADS holders' ability to receive a return on their investment will depend on any future appreciation in the market value of our ADSs. There is no guarantee that our ordinary shares or ADSs will appreciate or even maintain the price at which our holders have acquired them.

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

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

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

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

However, our ADS holders in the United States are not entitled to exercise or sell such pre-emptive subscription rights related to the ordinary shares, which they represent unless we register the pre-emptive subscription rights and the securities to which the pre-emptive subscription rights relate under the Securities Act or an exemption from the

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

Item 4 Information on the Company

A. History and Development of the Company

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

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

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

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

B. Business Overview

Overview

We are applying our innovative TransCon technologies to build a leading, fully integrated biopharmaceutical company and develop a pipeline of product candidates with potential best-in-class profiles to address unmet medical needs. We have created a portfolio of potential best-in-class rare disease endocrinology product candidates to address unmet medical needs by utilizing our TransCon technologies with clinically validated parent drugs. We currently have three product candidates in clinical development in rare endocrine diseases and we are advancing multiple preclinical candidates in oncology, our second therapeutic area of focus. We are also working to apply our TransCon technology platform in additional therapeutic areas to address unmet patient needs.

Our most advanced investigational product candidate, TransCon hGH (adopted nonproprietary name lonapegsomatropin), is in development as a once-weekly long-acting prodrug of recombinant human growth hormone, also referred to as somatropin or hGH, as a potential treatment for pediatric and adult growth hormone deficiency, or GHD. Our phase 3 pediatric program for TransCon hGH consists of the heiGHt, fliGHt and enliGHten Trials. Our results from the pivotal, phase 3 heiGHt Trial demonstrated a statistically significant increase in annualized height velocity, or AHV, compared to daily hGH at 52 weeks, and showed a safety profile comparable to that of daily hGH in pediatric subjects who were treatment-naïve.

Nearly all subjects who completed the heiGHt or fliGHt Trials have enrolled in the open-label extension study, or the enliGHten Trial, which is designed to provide long-term safety data to support the planned regulatory filings for TransCon hGH. We initiated the enliGHten Trial in 2017 as the first subjects began to roll over from the heiGHt Trial, and we have enrolled approximately 300 subjects, which we believe will form a safety database consistent with input received from regulatory authorities.

In September 2019, we completed the last subject visit forming the two-year follow up for the TransCon hGH phase 3 program in pediatric GHD. These data will form the safety database to support submission of a Biologics License Application, or BLA, to the U.S. Food and Drug Administration, or the FDA, for TransCon hGH to treat pediatric GHD, which we expect to submit in the second quarter of 2020, as well as submission of a Marketing Authorisation Application to the European Medicines Agency expected in the fourth quarter of 2020.

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

We believe that TransCon hGH, if approved, may offer a once-weekly therapy for pediatric and adult GHD with the potential to improve outcomes compared to currently approved daily hGH. If approved, we believe TransCon hGH may reduce the burden of daily treatment by requiring significantly fewer injections, which we believe may improve compliance and treatment outcomes. After receiving feedback from the FDA, we have filed an IND amendment to initiate a global, phase 3 trial in subjects with adult GHD and we intend to pursue other indications for TransCon hGH consistent with our strategy to create sustainable growth.

We are also using our TransCon technology platform to develop TransCon PTH, an investigational once-daily long-acting prodrug of parathyroid hormone, or PTH, as a potential treatment for adult hypoparathyroidism, a rare endocrine disorder of calcium and phosphate metabolism. We completed a phase 1 trial in healthy subjects in 2018, the results of which were consistent with our target product profile for TransCon PTH as a “true” replacement therapy. In this trial, TransCon PTH showed the predicted pharmacokinetic and pharmacodynamic response, suggesting the ability to normalize serum and urinary calcium levels in patients with hypoparathyroidism.

Our ongoing phase 2 PaTH Forward Trial is evaluating the safety, tolerability and efficacy of three fixed doses of TransCon PTH using a ready-to-use prefilled pen device. The goal of PaTH Forward is to identify a starting dose (15, 18, or 21 µg per day) for a pivotal phase 3 trial, establish a titration regimen for complete withdrawal of standard of care (i.e., active vitamin D and calcium supplements), and evaluate TransCon PTH control of serum and urinary calcium. In February 2020, we completed enrollment of the trial with 59 subjects and we expect to report top-line data from the one-month blinded portion of the PaTH Forward Trial in mid-April 2020. Following evaluation of Phase 2 data from the PaTH Forward Trial, we expect and plan to initiate a global phase 3 program for TransCon PTH in the fourth quarter of 2020, including trial sites in the United States, Canada, Europe and Asia-Pacific, including Japan.

In June 2018, we were granted Orphan Drug Designation, or ODD, by the FDA for TransCon PTH. ODD is provided to drugs that are intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. We believe TransCon PTH, if approved, may provide patients suffering from hypoparathyroidism with a PTH replacement therapy that is designed to address both the short-term symptoms and long-term complications of the disease.

We are also developing TransCon CNP, an investigational long-acting prodrug of C-type natriuretic peptide, or CNP, as a potential therapeutic option for achondroplasia, the most common form of dwarfism. TransCon CNP is designed to provide continuous CNP exposure with the goal of optimizing efficacy with a safe and convenient once-weekly dose. Currently, there are no medical therapies for achondroplasia approved by the FDA. In November 2018, we reported preliminary results from a phase 1 trial in healthy adult subjects, which supported our target product profile for TransCon CNP. In February 2019, we were granted ODD by the FDA for TransCon CNP. Following successful submission of an IND application in July 2019, we initiated the phase 2 ACcomplisH Trial to evaluate safety and efficacy of TransCon CNP in children (ages 2-10 years) with achondroplasia. The company continues to work towards escalating sequential dose cohorts throughout the year, while ensuring the safety of subjects during the current pandemic and access to physicians for future monitoring visits. Our goal is to develop TransCon CNP as a safe and effective therapeutic option for achondroplasia and potentially other related growth disorders.

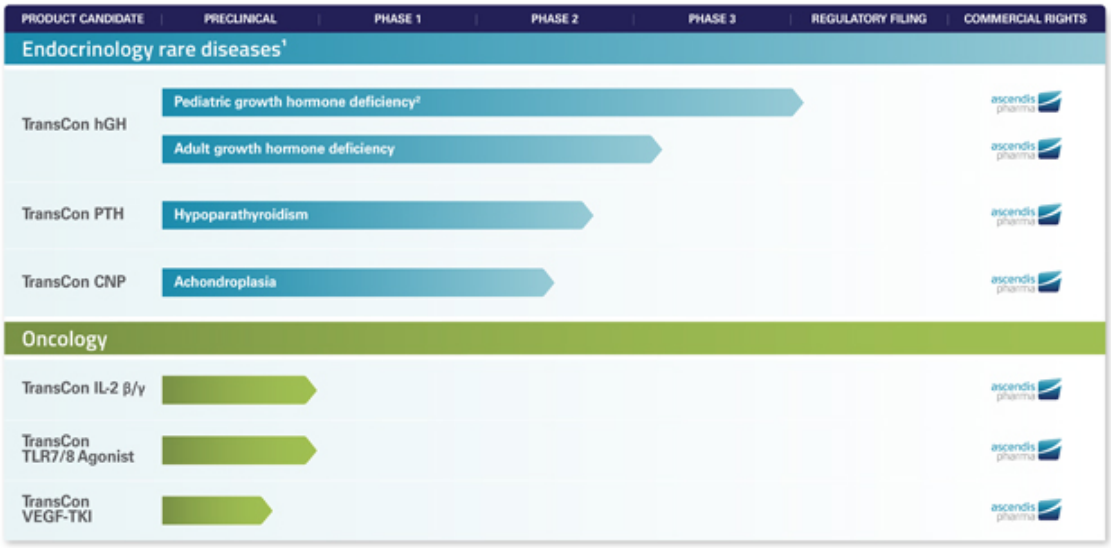
In addition to our pipeline of candidates in rare endocrine disorders, in January 2019, we established oncology as our second independent therapeutic area of focus for our TransCon technologies. In June 2019, we announced three of our oncology product candidates and reported preclinical data supporting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

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

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

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

TransCon Product Candidate Pipeline



1. Excludes rights granted to VISEN Pharmaceuticals in Greater China
2. In phase 3 development for pediatric growth hormone deficiency in Greater China through VISEN Pharmaceuticals

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

We maintain an intellectual property portfolio comprising over 160 issued patents and approximately 335 patent applications as of December 31, 2019 with claims directed to composition of matter, process, formulation and/or methods-of-use for our product candidates, including a product-specific device and core TransCon technologies. In addition, Sanofi has granted us rights that enable us to freely commercialize all improvements to the TransCon technologies developed by Sanofi outside of the field of diabetes. Other than the rights we have granted to Sanofi relating to the field of diabetes and to Visen as noted above, we hold worldwide rights to our TransCon technologies and owe no third-party royalty or milestone payment obligations with respect to our TransCon technologies or any of our product candidates. While our TransCon prodrugs may incorporate already approved parent drugs, each of our product candidates is a new molecular entity and is therefore eligible to be granted new intellectual property rights, including new composition of matter patents.

Our Strategy

Our goal is to build a fully integrated biopharmaceutical company by applying our TransCon technology platform to create a pipeline of proprietary products. Our algorithm for product innovation focuses on identifying indications that have an unmet medical need, have a clinically validated parent drug or pathway, are suitable to our TransCon technologies, have a clearly differentiated product, have a potential established development pathway and have a large potentially addressable market.

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

For the longer term, our aim is to utilize our product innovation algorithm to advance into new therapeutic areas and create sustainable growth through multiple approaches. We have established oncology as our second therapeutic area of focus and intend to select a third independent therapeutic area as part of our Vision 3x3 strategic roadmap through 2025, which was introduced in January 2019.

The key elements of Vision 3x3 include to:

- obtain regulatory approval for three independent endocrinology rare disease products: TransCon hGH for pediatric GHD, TransCon PTH for adult hypoparathyroidism and TransCon CNP for achondroplasia;
- create further growth of the company’s endocrinology rare disease pipeline through establishing global clinical reach either directly or through partnerships, pursuit of 9 total indications, and, label optimization and lifecycle management activities;
- establish a global commercial presence for the endocrinology rare disease franchise by building an integrated commercial business in North America and select European countries, and establishing relationships through partners with local expertise and infrastructure in other geographic areas; and
- creation of a third independent therapeutic areas with a diversified pipeline built on our TransCon technology platform and the company’s unique algorithm for product innovation.

TransCon Technologies

Overview

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

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

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

Efficacy Benefits

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

Safety and Tolerability Benefits

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

Development Benefits

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

Intellectual Property Benefits

- New composition of matter patents

TransCon Technology Components

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

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

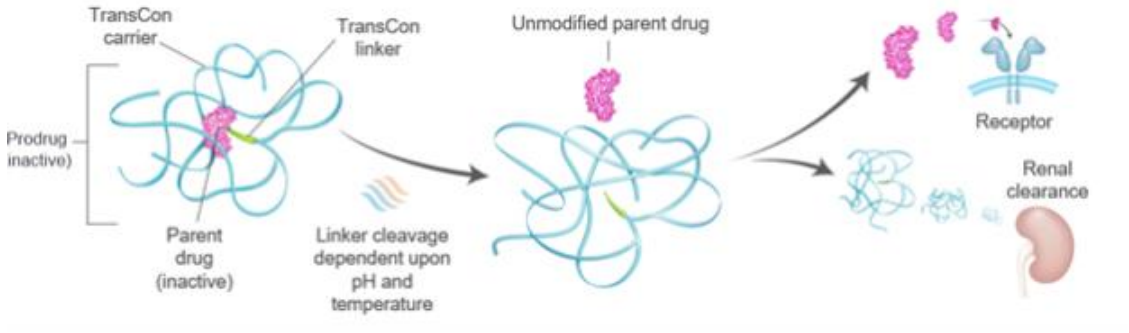
TransCon Linkers

Our TransCon linkers are reversible linkers that enable the transient conjugation of a broad range of therapeutics, including proteins, peptides and small molecules, to our TransCon carriers. We have a large library of TransCon linkers that are applicable to various types of parent drugs, and that can be tailored to achieve half-life extension enabling daily, weekly, monthly and half-yearly dosing, and customize the pharmacokinetic, or PK, profile for each individual product candidate to potentially optimize therapeutic effect. TransCon linkers are self-cleaving through a process called intra-molecular assisted cleavage, which causes the linker to release the unmodified parent drug. We can tailor the release properties of the linker to a given therapeutic indication and parent drug by modifying the linker structures. We believe the self-cleaving process of our linker avoids many of the shortcomings of conventional prodrug technologies, which often depend on metabolic processes, such as enzymatic degradation, to convert the prodrug into the active drug. The rate of metabolic conversion of prodrugs in these types of processes may differ between patients, and even within different tissues in the same patient. As a result, conventional prodrugs do not always offer predictable release of the parent drug. Our TransCon linkers predictably release an unmodified active parent drug at predetermined rates governed by physiological pH and temperature conditions, which are tightly regulated in the body. Consequently, we can design our prodrugs to release the unmodified parent drug at predictable rates.

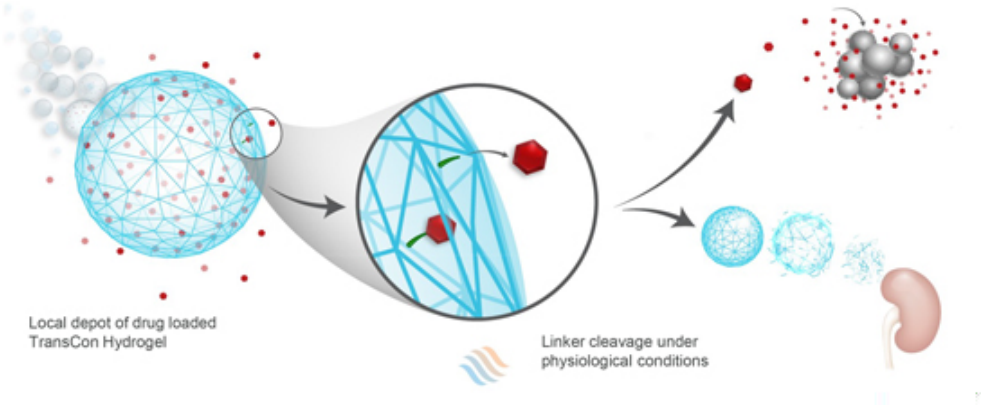
TransCon Carriers

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

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



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



Parent Drug

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

This approach has enabled us to generate a pipeline of product candidates to address significant unmet medical needs and to become potential sources of significant revenue for our company. Because our TransCon technologies

release an unmodified drug with established clinical safety and efficacy, we believe we may benefit from a higher development and regulatory success rate as compared to development of drug compounds without established biology.

TransCon Product Candidates - Endocrinology

TransCon Growth Hormone (hGH)

Market Opportunity in GHD

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

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

Despite the demonstrated benefits of hGH therapy, adherence continues to be a challenge, as patients treated with daily hGH typically receive thousands of injections over the course of many years. Published studies have shown that the majority of patients on a daily hGH regimen are not fully adherent with their daily dosing schedule, and therefore fail to achieve expected treatment outcomes. According to a 2018 study (Graham et al), as many as 7 out of 10 pediatric patients are non-adherent to daily growth hormone therapy, which may result in significant reductions in the degree of growth and suboptimal outcomes.

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

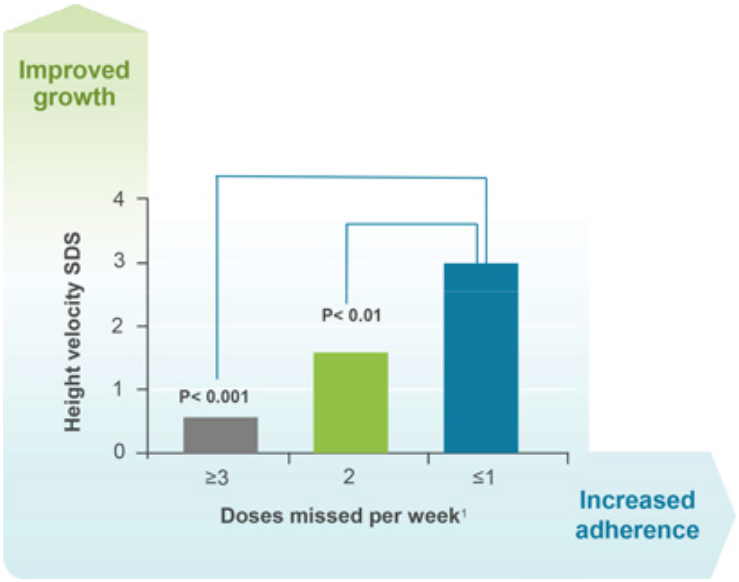


Figure 1. Negative impact of poor compliance on growth response. Patients missing two or more injections per week have a statistically significant reduction in height velocity. A result is considered statistically significant when the p-value, representing the probability that random chance could explain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

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

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

Global annual sales from currently marketed hGH products are currently estimated at approximately $4 billion. We believe a significant market opportunity exists for a long-acting version of hGH with comparable efficacy, safety and tolerability as daily hGH products. We are developing TransCon hGH as a once-weekly somatropin (hGH) therapy with a target profile designed to have comparable efficacy, safety and tolerability to daily hGH, but with a dosing regimen that could improve adherence and overall health.

Competitive Landscape for Long-Acting Growth Hormone Therapies

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

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

There are currently no long-acting growth hormone treatment options available in the United States or Europe. A permanently PEGylated long-acting growth hormone developed by GeneScience Pharmaceuticals Co., Ltd. is available in China and the Somatropin Biopartners product (LB03002), is available in Korea.

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

Our Solution: TransCon hGH

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

We believe our once-weekly TransCon hGH has the same mode of action and distribution into key growth hormone-responsive tissues, such as brain, bone, muscle, liver and fat tissue, as the hGH administered from daily injections and endogenous growth hormone. We use daily growth hormone as an active comparator in our clinical studies, allowing us to directly compare the activity of TransCon hGH to daily growth hormone in an identical clinical setting.

Clinical Development of TransCon hGH for Pediatric GHD

Our phase 3 pediatric program for TransCon hGH consists of the heiGHt, fliGHt and enliGHten Trials. In March 2019, we reported top-line results for the heiGHt Trial, in which TransCon hGH was observed to have superior efficacy (as demonstrated by a statistically significant increase in AHV at 52 weeks) and comparable safety and tolerability to that of daily hGH.

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

The heiGHt Trial was a randomized, open-label, active-controlled phase 3 registrational trial that enrolled 161 children with GHD who had not previously been treated. Subjects received either once-weekly TransCon hGH (0.24 mg/kg/week) or daily injections of Genotropin® at 34 µg/kg/day (0.24 mg/kg/week) with a 2:1 randomization. The primary endpoint was annualized height velocity (AHV) at 52 weeks, with a non-inferiority analysis comparing the difference between the two treatment groups. Two subjects, one from each arm, withdrew from the trial prior to the final visit.

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

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

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

Additional analyses from the heiGHt Trial showed:

- No neutralizing antibodies detected, and post-baseline low level of low-titer non-neutralizing anti-hGH binding antibodies was similar between the two arms (7 [6.7%] in TransCon hGH vs. 2 [3.6%] in Genotropin arm).
- Height SDS at 52 weeks increased over baseline by 1.10 for TransCon hGH and by 0.96 for the daily hGH, with the treatment difference increasing at each visit over 52 weeks.

- Body Mass Index (BMI) was in the normal range over 52 weeks in both the TransCon hGH group (with a mean increase in BMI SDS from -0.32 at baseline to -0.03 at Week 52) and in the daily hGH group (with a mean BMI SDS decrease from -0.14 at baseline to -0.40 at week 52).
- Mean hemoglobin A1c values were generally stable over the course of the trial and remained within the normal range for both arms.
- Model-derived mean average insulin-like growth factor-1 (IGF-1) SDS values were 0.61 for TransCon hGH and 0.01 for the daily hGH at week 52.
- Adverse events leading to dose reduction (IGF-1 levels or clinical symptoms) occurred twice in the TransCon hGH arm (representing 1.9 percent) and once in the daily hGH arm (representing 1.8 percent).
- Observed change in bone age over 52 weeks from baseline was 1.36 years for the TransCon hGH arm and 1.35 years in the daily arm.

Additional Clinical Trials of TransCon hGH

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

Additionally, in May 2019, we announced preliminary data from the single arm phase 3 fliGHt Trial of TransCon hGH, which was designed to create additional exposures and expand the safety database for TransCon hGH in pediatric subjects. In this single arm open-label trial, subjects switched from daily hGH to weekly TransCon hGH with a primary objective of evaluating the safety and tolerability of TransCon hGH in subjects with pediatric GHD. The trial enrolled 146 subjects, and indicated treatment with TransCon hGH was safe and well-tolerated in those with pediatric GHD who were previously treated with commercially-available daily growth hormone therapies. In the trial, the safety profile of TransCon hGH was similar to the published safety profile of daily growth hormone therapies. We believe the results from the fliGHt Trial support switching to once-weekly TransCon hGH from a daily hGH, and also provide evidence supporting the tolerability of TransCon hGH in subjects under three years of age.

Nearly all subjects who completed the heiGHt or fliGHt Trials have enrolled in the open-label extension study, the enliGHten Trial, which is designed to provide long-term safety data to support the planned regulatory filings for TransCon hGH. We initiated the enliGHten Trial in 2017, and approximately 300 pediatric subjects enrolled. We expect data from enliGHten will form a safety database consistent with the input we have received from regulatory authorities.

In September 2019, we completed the last subject visit forming the two-year follow up for the TransCon hGH phase 3 program in pediatric GHD. These data, including results from approximately 300 subjects treated with TransCon hGH (approximately 300 for six months, 120 for 12 months and 45 for 24 months), will form the safety database to support submission of a BLA to the FDA for TransCon hGH for the treatment of pediatric GHD expected in the second quarter of 2020, as well as submission of a Marketing Authorisation Application to the European Medicines Agency, expected in the fourth quarter of 2020.

Additionally, in January 2020, we presented 78-week analysis of data from the ongoing enliGHten Trial, including follow-up on subjects from heiGHt who continued into enliGHten. The data showed

maintenance of a treatment advantage in subjects initially treated with TransCon hGH beyond the first year of therapy. The safety results, which were comparable to Genotropin in the phase 3 heiGHt Trial, were consistent across the phase 3 clinical trials.

Proprietary Auto-injector Development

As part of our effort to improve treatment compliance among children with GHD, we are developing a state-of-the-art auto-injector for the administration of TransCon hGH. In May 2019, we introduced the auto-injector into the enliGHten Trial and we expect to make it available to patients in conjunction with a potential commercial launch. As of January 2020, over 160 subjects have used auto-injector and dual-chamber cartridges in the enliGHten extension trial, which we believe meets our objective of collecting required usability data to support inclusion of the auto-injector as part of our initial BLA submission.

The auto-injector provides for room temperature storage, includes an empty-all design and is expected to last for at least four years. With simple operation, the device has a single, low-volume injection for the majority of patients of less than 0.6 mL and requires a small, 31-gauge needle that is only 4 millimeters in length, which is comparable to needles used to administer daily hGH. We are also working on strategies that will enable the auto-injector to integrate with the digital healthcare system, including Bluetooth connectivity features to allow for easy tracking of dosing compliance over time.

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

Clinical Development of TransCon hGH in Adults

We have successfully completed a phase 2, European, multi-center, multiple dose, open-label, active-controlled, study to examine the safety, tolerability, pharmacokinetics and pharmacodynamics in 37 adult male and female subjects with GHD. We have also completed several phase 1 trials in healthy adult subjects.

Results from the Phase 2 Trial in Adults with GHD

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

In this study, serum levels of somatropin (hGH) increased proportionally with the administered dose and the maximum serum concentration of somatropin released from TransCon hGH was comparable to the levels achieved by daily hGH injections.

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

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

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

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

Future Development Plans

Following discussions with FDA, we have submitted an IND amendment to initiate the global, phase 3 foresiGHt Trial in adult GHD. The foresiGHt Trial is expected to begin enrollment later this year, and aims to demonstrate the metabolic benefits of TransCon hGH in adults, with the primary objective to evaluate change in trunk fat percentage.

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

As part of our strategy to establish global reach, we also intend to initiate a phase 3 trial in pediatric GHD in Japan in fourth quarter of 2020.

TransCon PTH

Market Opportunity in Hypoparathyroidism

Hypoparathyroidism, or HP, is a rare endocrine disorder characterized by deficient or absent parathyroid hormone, or PTH, affecting approximately 200,000 patients in the U.S., Europe, Japan and South Korea. The most common cause in approximately 75% of cases is inadvertent removal or damage to the parathyroid tissue during neck surgery. Patients with HP cannot adequately regulate calcium and phosphate metabolism and suffer from low calcium and elevated phosphate levels in the blood. The condition results in a diverse range of physical, cognitive and emotional symptoms. Short term symptoms include weakness, severe muscle cramps (tetany), abnormal sensations such as tingling, burning and numbness (paresthesia), memory loss, impaired judgment and headache. Over the long term, treatment with the current standard of care (SoC) can increase risk of major complications, such as extraskeletal calcium depositions occurring within the brain, lens of the eye, and kidneys, which can lead to impaired renal function. Patients often experience decreased quality of life.

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

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

HP also poses a high burden on the healthcare system despite current standard of care. For example, one survey of 374 patients showed that 72% experienced more than 10 symptoms in the preceding 12 months, with symptoms experienced for a mean of 13 ± 9 hours a day. Other studies showed that 79% of HP cases require hospitalizations and that patients with the disorder results have a four-fold increase in the risk of renal disease compared to healthy controls. Patients often experience decreased quality of life. We conducted a survey of 42 patients which found that 100 percent of subjects reported negative psychological impacts, interference with daily life and impact on physical functioning from HP, and that 76 percent were either no longer able to work or experienced interference with work productivity.

An effective PTH replacement therapy that fully addresses the condition is not widely available to patients with HP. In 2015, NATPARA, PTH(1-84), was approved for once-daily subcutaneous injection as an adjunct to vitamin D and calcium in patients with hypoparathyroidism. NATPARA was voluntarily recalled in September 2019 in the U.S. and is now only available to a limited number of seriously-ill patients through a Special Use Program offered by its manufacturer, Takeda Pharmaceutical Company. We are also aware of several academic groups and companies working on making longer-acting agonists of the PTH receptor, or PTH1R. In addition, other companies and groups are developing or commercializing therapies for hypoparathyroidism, including Shire, Chugai Pharmaceutical Co., Ltd., Entera Bio, Extend Biosciences, Massachusetts General Hospital, Alizé Pharma and Eli Lilly and Company.

Teriparatide, PTH(1-34), approved since 2002 for the treatment of osteoporosis, has sometimes been used for treatment of hypoparathyroidism using multiple daily injections, despite not being approved for this indication. Clinical research conducted by the NIH of subjects receiving continuous exposure to PTH(1-34), administered by an infusion pump, has demonstrated simultaneous normalization of sCa and urinary calcium, as well as normalization of bone turnover.

Our Solution: TransCon PTH

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

With once-daily dosing, we believe this substantial half-life extension of PTH could more closely reflect the physiological levels of PTH observed in healthy individuals thereby maintaining blood calcium levels and normalizing urinary calcium excretion. Pharmacokinetic data from multiple ascending dose (MAD) cohorts in our phase 1 trial of TransCon PTH in healthy subjects demonstrated an infusion-like profile of free PTH. By providing steady levels of PTH in the physiological range, we believe TransCon PTH can address the fundamental limitations of short-acting PTH molecules, such as NATPARA, or PTH(1-84), and Teriparatide, or PTH(1-34) and become a highly differentiated therapy for HP.

Clinical Development of TransCon PTH for Adult Hypoparathyroidism

Our ongoing phase 2 PaTH Forward Trial is evaluating the safety, tolerability and efficacy of three fixed doses of TransCon PTH using a ready-to-use prefilled pen device. The goal of PaTH Forward is to identify a starting dose (15, 18, or 21 µg per day) for a pivotal phase 3 trial, establish a titration regimen for complete withdrawal of standard of care (i.e., active vitamin D and calcium supplements), and evaluate TransCon PTH control of serum and urinary calcium.

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

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

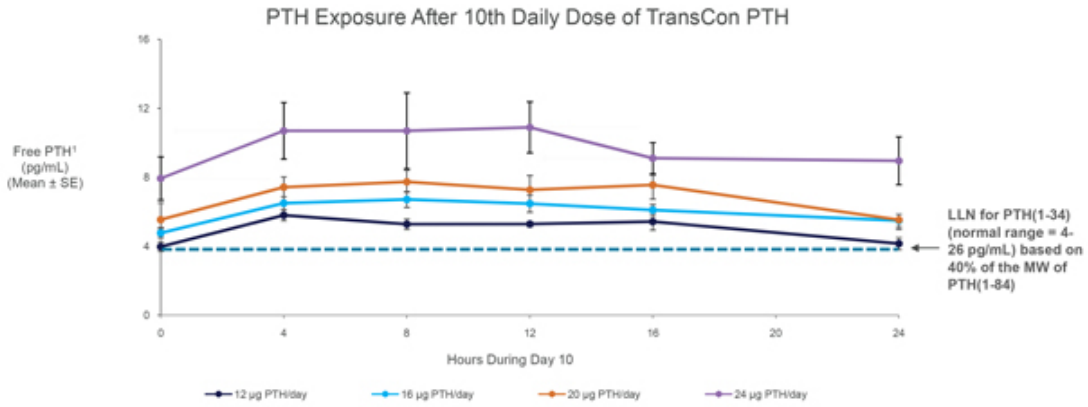


Figure 3. TransCon PTH daily dosing for 10 days of 12, 16, 20 and 24 µg per day. TransCon PTH daily dosing for 10 days provided a flat infusion-like profile with a low PTH peak-to-trough ratio at day 10.

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

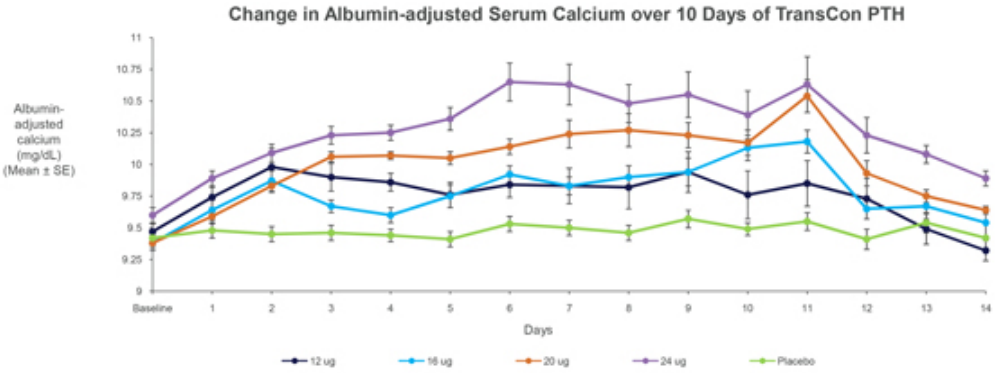


Figure 4. Serum calcium over 10 days of TransCon PTH. TransCon PTH daily dosing for 10 days provided a dose-dependent increase of serum calcium.

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

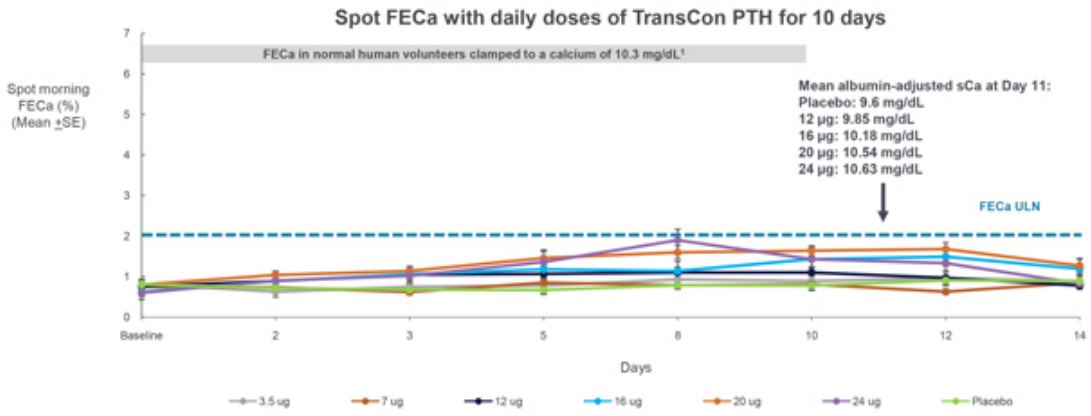


Figure 5. Control of urinary calcium with multiple doses of TransCon PTH.

The final results of the phase 1 trial were consistent with our target product profile for TransCon PTH, showing the predicted pharmacokinetic and pharmacodynamic response, and suggesting the ability to normalize serum and urinary calcium levels in patients with hypoparathyroidism. We believe TransCon PTH may provide patients suffering from hypoparathyroidism with a PTH replacement therapy that is designed to address both the short-term symptoms and long-term complications of HP.

In June 2018, we were granted Orphan Drug Designation, or ODD, by the FDA, for TransCon PTH. The FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

We initiated the phase 2 PaTH Forward Trial in adult subjects with hypoparathyroidism in the first quarter of 2019. PaTH Forward is evaluating the safety, tolerability and efficacy of three fixed doses of TransCon PTH using a ready-to-use prefilled pen device. The goal of PaTH Forward is to identify a starting dose (15, 18, or 21 µg per day) for a pivotal phase 3 trial, establish a titration regimen for complete withdrawal of standard of care (i.e., active vitamin D and calcium supplements), and evaluate TransCon PTH control of serum and urinary calcium. Following the one-month blinded portion of PaTH Forward, subjects entered an open-label extension where they will receive a customized maintenance dose of TransCon PTH (6 to 30 µg per day) titrated to optimize their calcium control and evaluated on the primary composite endpoint, both as planned for phase 3.

On November 14, 2019, we announced an expansion of the patient population in the ongoing PaTH Forward Trial to facilitate enrollment of subjects affected by the NATPARA® recall, a parathyroid hormone. Previously, patients treated with NATPARA were required to undergo a long washout period prior to entering screening. In response to the recall of NATPARA in the United States, we evaluated opportunities to help enroll patients affected by the recall. Following the protocol addendum, patients previously treated with NATPARA in the United States were able to utilize an expedited process to enroll in PaTH Forward. In February 2020, we completed enrollment of the expanded trial with 59 subjects and we expect to report top-line data from the one-month blinded portion of the PaTH Forward Trial in mid-April 2020, with six-month data from the open-label extension phase expected to be reported during the third quarter of 2020. Final enrollment of PaTH Forward included 17 subjects previously treated with NATPARA.

On January 12, 2020, we reported preliminary data from patient diaries on the first 8 subjects completing 4 weeks of follow-up in the open-label extension portion, which showed that all subjects were completely off current standard of care. All 8 subjects no longer required active vitamin D, and 7 of 8 subjects no longer required calcium supplements (one subject taking < 500 mg calcium). 59 subjects completed the blinded portion, and 58 subjects continued in the open-label extension, with one subject withdrawing for reasons unrelated to safety or efficacy of the study drug.

Following evaluation of Phase 2 data from the PaTH Forward Trial, we expect and plan to initiate a global phase 3 trial for TransCon PTH in the fourth quarter of 2020, including trial sites in the United States, Canada, Europe and Asia-Pacific, including Japan.

TransCon CNP

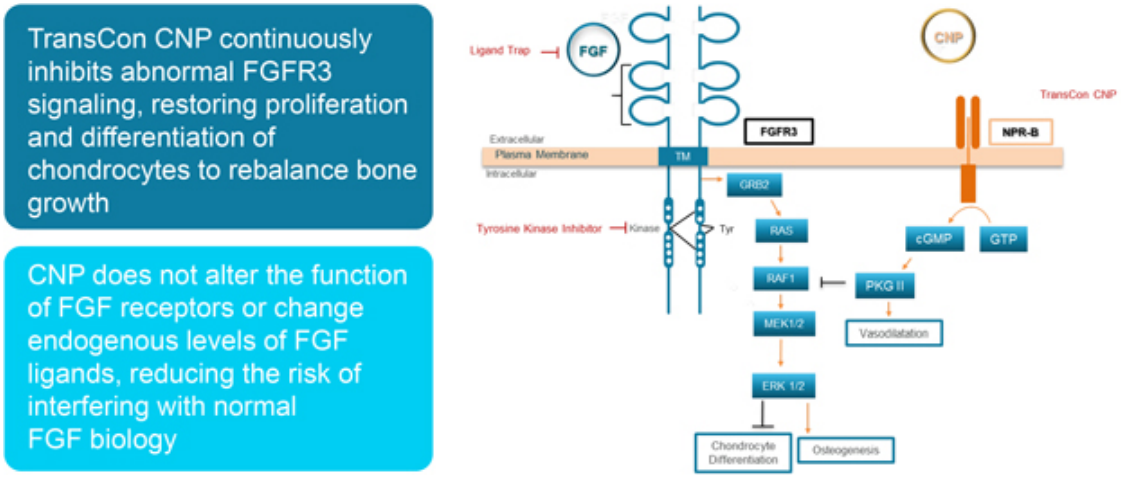
Market Opportunity in Achondroplasia

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

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

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

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



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

Figure 6. The role of a defect in the FGFR3 signaling pathway in the development of achondroplasia is well understood.

Our Solution: TransCon CNP

Endogenous CNP has an extremely short half-life of only approximately two minutes. Vosoritide, a CNP analogue, has been developed to provide better stability of CNP, and has a half-life of about 20 minutes. In a phase 3 trial, vosoritide also demonstrated a statistically significant change in growth velocity from baseline over one year in children treated with vosoritide compared to placebo.

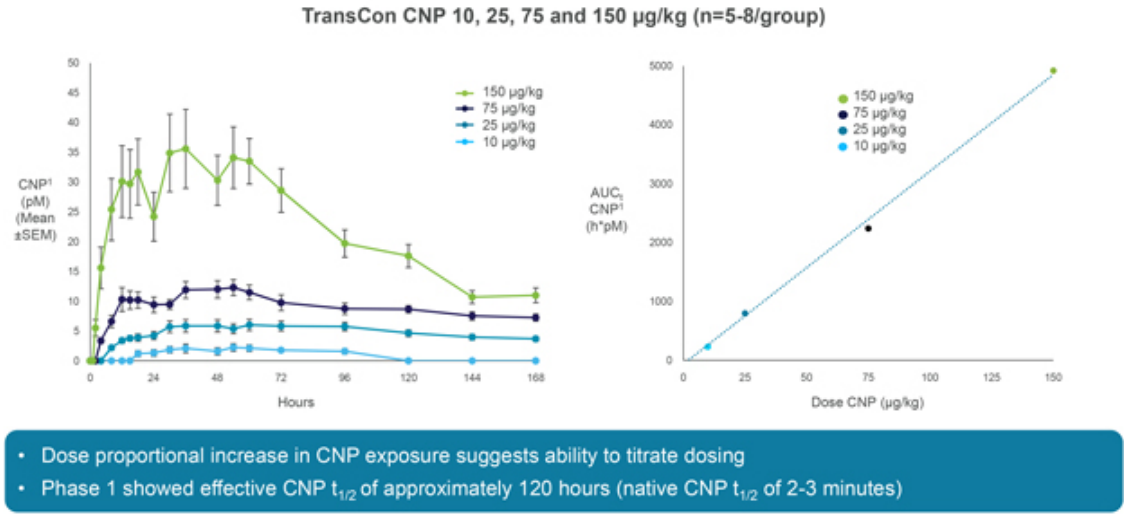
However, in addition to limited efficacy, short-acting CNP and CNP analogues that result in high Cmax levels may cause adverse cardiovascular events. As achondroplasia is caused by an FGFR3 mutation that chronically inhibits growth, we expect a more constant CNP exposure at lower Cmax to correlate with better therapeutic outcomes, with lower cardiovascular risk. TransCon CNP is an investigational long-acting prodrug of C-type natriuretic peptide designed to provide continuous CNP exposure at therapeutic levels with a well-tolerated and convenient once-weekly dose. It is being developed for the treatment of children with achondroplasia. TransCon CNP is designed to provide effective shielding of CNP from neutral endopeptidase degradation in subcutaneous tissue and the blood compartment, minimize binding of CNP to the NPR-C receptor to decrease clearance, reduce binding of CNP to the NPR-B receptor in the cardiovascular system to avoid hypotension, and release unmodified CNP, which is small enough in size to allow effective penetration into growth plates.

Clinical Development of TransCon CNP for Achondroplasia

TransCon CNP is currently being evaluated in a global phase 2 trial, known as the ACcomplisH Trial, which is designed to evaluate the safety and efficacy of TransCon CNP in children (ages 2-10 years) with achondroplasia.

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

The results showed TransCon CNP provided continuous exposure to CNP with a pharmacokinetic profile designed to provide efficacy with once-weekly dosing. No serious adverse events were reported in the trial and TransCon CNP was generally well tolerated at doses up to 150 µg/kilogram. Mean orthostatic changes in vital signs appeared unrelated to TransCon CNP exposure and were consistent between placebo and TransCon CNP cohorts. Mean resting blood pressure and heart rate were unchanged from pre-dose at all time points, in all cohorts. Injections were well tolerated in all dose cohorts. No anti-CNP antibodies were detected in any subjects.



1 CNP measured as CNP-38.

Figure 7. Pharmacokinetic results for TransCon CNP 10, 25, 75 and 150 µg/kg administered as a once-weekly subcutaneous injection are presented.

Following completion of the phase 1 trial, we initiated the ACcomplisH Trial to evaluate the safety and efficacy of TransCon CNP in approximately 60 children with achondroplasia (ages 2 to 10 years). The primary efficacy endpoint is annualized height velocity at 12 months. Key secondary and additional endpoints include body proportionality and change in BMI, both evaluated after 12 months of weekly TransCon CNP treatment, and patient reported outcome (PRO) measures. The company continues to work towards escalating sequential dose cohorts throughout this year. In parallel, we are conducting the ACHieve Study, a natural history study designed to gain insight into the experience of pediatric patients with achondroplasia. ACHieve will study growth velocity, body proportionality, and comorbidities over time of children with achondroplasia up to 8 years old. No study medication will be administered.

In February 2019, we were granted ODD by the FDA for TransCon CNP for the treatment of achondroplasia. Our goal is to develop TransCon CNP as a safe and effective therapeutic option for achondroplasia and potentially other related growth disorders.

TransCon Product Candidates - Oncology

Market Opportunity in Oncology

Cancer remains a major unmet medical need and the incidence of many cancer types continues to rise. Improved understanding of the cellular and molecular mechanisms involved in anti-tumor immune responses has fueled the rapid growth of immuno-oncology therapeutics. In particular, immune checkpoint inhibitors, such as anti-PD-1, anti-PD-L1 and anti-CTLA-4 antibodies, have provided new therapeutic options for patients who did not respond to previous therapies. Supported by these and other advancements, oncology is now the largest therapy class in terms of revenue in pharmaceutical industry, with worldwide prescription drug and over-the-counter sales of $124 billion in 2018 with projected growth to $237 billion in 2024.

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

Our Solution: TransCon Technologies for Oncology

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

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

Our TransCon product candidates in oncology are designed for sustained systemic or intratumoral administration to provide durable and potent anti-tumor effects. TransCon product candidates can be designed to facilitate all the critical steps of the cancer immunity cycle that lead to eradication of malignant cells. We believe these product candidates have the potential to optimize the efficacy of clinically validated therapies while limiting adverse effects.

For example, many therapies are administered at the maximum tolerated dose, and the ability to deliver therapies directly to the tumor may improve both tolerability and efficacy, as high local drug concentration may be achieved, while maintaining low systemic exposure. In addition, TransCon product candidates are designed for sustained release and, hence, may allow for reduced frequency of dosing, enabling treatment of tumor types that cannot be easily accessed for frequent injection.

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

Development of TransCon Product Candidates in Oncology

Our goal is to improve treatment efficacy while limiting or reducing toxicity by applying TransCon technologies to clinically validated pathways, using our unique algorithm for product innovation. We are conducting nonclinical studies within the field of oncology to explore multiple potential product candidates and evaluate systemic as well as localized delivery systems using our TransCon technologies.

In June 2019, we reported nonclinical data for three of our oncology programs:

- TransCon IL-2 ß/g is designed for prolonged exposure of an IL-2 variant that selectively activates the IL-2Rß/g with low binding to IL-2Rα. This product candidate is designed to provide potent anti-tumor activity and to have reduced risk of toxicity, such as vascular leak syndrome.
- TransCon TLR7/8 Agonist is designed for sustained release of TLR7/8 agonist, resiquimod, and intended for intratumoral administration. This product candidate is designed to provide potent activation of the innate immune system in the tumor and draining lymph nodes and to have low risk of systemic toxicity.
- TransCon VEGF-TKI is designed for sustained release of a VEGF-TKI molecule, axitinib, and intended for intratumoral treatment. The product candidate is designed to enable high intratumoral concentrations of axitinib that are not achievable via oral route, potentially improving efficacy and avoiding toxicities of oral treatments that often result in treatment interruptions and discontinuations.

We are evaluating multiple TransCon product candidates in nonclinical research studies for the treatment a variety of tumor types. Examples of TransCon product candidates under evaluation include stimulators of innate and adaptive immunity, as well as modulators of the tumor environment. We are exploring systemic and intratumoral administration both as a monotherapy and as a component of combination regimens.

We believe these programs have potential to target multiple steps of the immunity cycle that drives the immune response against tumor cells. Our goal is to file an IND or equivalent in oncology in the fourth quarter of 2020.

Strategic Collaborations

We also engage in strategic collaborations to further leverage our TransCon technology platform in certain geographies with market-leading biopharmaceutical companies. These collaborations aim to further monetize both our TransCon technology platform and our internal product candidates, particularly into therapeutic areas where we believe a partner may have more expertise, capability and capital.

In addition, we may choose to pursue a collaboration to develop and market our internal, wholly-owned product candidates in geographic markets outside our core focus of the United States and Europe.

Strategic Investment

VISEN Pharmaceuticals

In November 2018, we announced the formation of VISEN Pharmaceuticals, or Visen, a company established to develop and commercialize our endocrinology rare disease therapies in the People’s Republic of China, Hong Kong, Macau, and Taiwan, or Greater China. In connection with the formation of Visen, we granted Visen exclusive rights to develop and commercialize certain product candidates based on our proprietary TransCon technologies, including TransCon hGH, TransCon PTH and TransCon CNP, in Greater China for use in all human indications, subject to

certain exceptions. As consideration for the rights granted to Visen, we received 50% ownership in the outstanding shares of Visen and concurrently with the rights we granted to Visen, entities affiliated with Vivo Capital and Sofinnova Ventures purchased shares in Visen for an aggregate purchase price of $40 million in cash. On October 25, 2019, Visen received approval of a clinical trial application for TransCon hGH from the Center for Drug Evaluation in China and initiated a phase 3 trial in pediatric growth hormone deficiency. In addition, Visen expects to initiate a phase 2 trial in children with achondroplasia during the fourth quarter of 2020.

Market Opportunity in China

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

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

Rights Agreements

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

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

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

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

Shareholders Agreement

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

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

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

Strategic Collaboration with Sanofi

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

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

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

Sanofi for convenience, all licenses granted to Sanofi would terminate and, if such termination is by Sanofi for convenience prior to IND approval of a product under the agreement, we may require Sanofi to assign back to us the assigned patent rights upon payment of a specified amount. Our collaboration agreement with Sanofi remains in effect; however, in December 2019 Sanofi announced it plans to end its investments in the field of diabetes.

Manufacturing

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

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

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

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

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

NOF Manufacturing and Supply Agreement

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

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

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

Carbogen Manufacturing and Supply Agreement

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

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

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

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

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

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

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

Vetter Pharma International GmbH

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

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

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

Fujifilm Commercial Supply Agreement

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

The Fujifilm Agreement is effective as of January 9, 2019. The initial term of the Fujifilm Agreement expires on December 31 in the year of the five-year anniversary of the first commercial sale of our TransCon hGH product candidate (the "Fujifilm Initial Term") unless earlier terminated. After the expiration of the Fujifilm Initial Term of the Fujifilm Agreement, the Fujifilm Agreement continues until it is terminated. The Fujifilm Agreement may be terminated (i) by either party for the other party's bankruptcy or insolvency-related events, (ii) by either party for the other party's uncured material breach or material breach that is not capable of remedy, (iii) by us after the Fujifilm Initial Term of the Fujifilm Agreement with two years written notice, or (iv) by Fujifilm after the Fujifilm Initial Term of the Fujifilm Agreement with five years written notice. We are entitled to terminate the Fujifilm Agreement with regards to the manufacture of recombinant hGH after one year following launch with two years written notice. In addition, the Fujifilm Agreement may be terminated by us in the event of a change in control of Fujifilm, where the new controlling entity is our competitor. The Fujifilm Agreement may also be terminated by either party for a continuing event of force majeure.

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

Lonza Tech Transfer and Manufacturing Agreement

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

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

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

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

Sharp Corporation Packaging and Supply Agreement

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

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

The Sharp Agreement contains, among other provisions, certain warranties by Sharp, provides for certain indemnification rights in favor of both parties and includes confidentiality provisions.

Competition

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

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

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

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

Intellectual Property

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

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

As of December 31, 2019, we own a total of 80 patent families, of which 26 are currently in their priority year or international phase and we own several granted patents in the United States (24), Europe (12), Australia (24), Canada (11), China (7), Israel (11), Indonesia (2), India (3), Korea (3), Malaysia (3), New Zealand (4), Japan (15), Mexico (10), Singapore (6), Russia (8) and South Africa (19) and have approximately 366 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, 2019 are summarized below and the expected expiration dates included in the summary below do not give effect to patent term extensions that may be available.

TransCon hGH

Our patent portfolio related to TransCon hGH includes seven patent families relating to different aspects of TransCon hGH and an additional nine patent families covering various aspects of the auto-injector device for administration of TransCon hGH. The first of these patent families is a composition of matter patent family directed to the particular stoichiometry of TransCon hGH and a related TransCon carrier. As of December 31, 2019, this patent family included patents granted in Europe and the United States. We expect any patents granted in this patent family to expire in October 2024.

The second of these patent families is a composition of matter patent family directed to a TransCon linker used in TransCon hGH. As of December 31, 2019, this patent family included patents granted in the United States, Europe, Australia, Canada, Japan and Mexico and included patent applications in Europe, the United States, and Brazil. We expect any patents granted in this patent family to expire in March 2025.

The third of these patent families is a composition of matter patent family directed to a broad class of TransCon hGH lead candidate structures. As of December 31, 2019, this patent family included patents granted in the United States, Europe, Australia, Canada, China, Israel, India, Japan, Mexico, Russia and South Africa and included patent applications in Europe, the United States, Brazil, Canada, India, Japan, Mexico and Russia. We expect any patents granted in this patent family to expire in April 2029.

The fourth of these patent families is a composition of matter patent family directed to specific dry pharmaceutical compositions comprising TransCon hGH. As of December 31, 2019, this patent family included patents granted in the United States, Europe, Australia, Canada, Israel, Mexico, Singapore and South Africa and included patent applications in the United States, Brazil, and India. We expect any patents granted in this patent family to expire in December 2030.

The fifth of these patent families is a composition of matter patent family directed to a broad class of TransCon hGH lead candidate structures. As of December 31, 2019, this patent family included a patent granted in South Africa and patent applications in the United States, Europe, Australia, Brazil, Canada, Israel, Japan, South Korea, Mexico, New Zealand, Russia and Singapore. We expect any patents granted in this patent family to expire in November 2035.

The sixth of these patent families is directed to a particular dosage regimen for long-acting growth hormone formulations. As of December 31, 2019, this patent family included patent applications in the United States and in Europe. We expect any patents granted in this patent family to expire in November 2035.

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

Seven of the nine patent families covering the auto-injector device with a filing date of December 29, 2016, includes patent applications in the United States, Europe, Australia, Canada, Japan and New Zealand as of December 31, 2019. We expect any patents granted from these patent families to expire in December 2036. As of December 31,

2019 the other two patent families covering the auto-injector device with a filing date of May 23, 2018 and June 29, 2018, respectively, include patent applications in the United States, Europe, the United Arab Emirates, Australia, Brazil, Canada, China, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore and South Africa. We expect any patents granted from these patent families to expire in March and June 2038, respectively.

TransCon PTH

Our patent portfolio related to TransCon PTH includes seven patent families relating to different aspects of TransCon PTH. The first of these patent families is a composition of matter patent family directed to the TransCon linker used in TransCon PTH. As of December 31, 2019, this patent family included granted patents in the United States, Europe, the United Arab Emirates, Australia, Canada, China, Israel, Japan, Mexico and South Africa and included patent applications in Europe, the United States, Brazil and Russia. We expect any patents granted in this family to expire in January 2029.

The second of these patent families is a composition of matter patent family directed to a broad class of TransCon PTH candidate structures. As of December 31, 2019, this patent family included patent applications in the United States, Europe, Australia, Brazil, Canada, China, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore and Thailand and a granted patent in South Africa. We expect any patents granted in this patent family to expire in February 2037.

The third and fourth of these patent families are method of treatment patent families directed to a particular dosage regimen. As of December 31, 2019, one of these patent families includes patent applications in the United States, Europe, Australia, Brazil, Canada, China, Israel, Indonesia, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore and Thailand and a granted patent in South Africa. The other one of these patent families includes patent applications in the United States, Europe, Australia, Canada, China and Japan. We expect any patents granted in this patent family to expire in September 2037.

The fifth of these patent families is a composition of matter family directed to PTH compounds exhibiting a beneficial pharmacokinetic profile. As of December 31, 2019, this patent family includes patent applications in the United States, Europe, Australia, Brazil, Canada, China, Israel, Japan, South Korea, Mexico, New Zealand, Russia and Singapore and a granted patent in South Africa. We expect any patents granted in this patent family to expire in September 2037.

The sixth patent family relates to a starting dose for treatment with reversible PTH conjugates. As of December 31, 2019, this patent family consists of an international application. We expect any patents granted from this patent family to expire in May 2039.

The seventh patent family relates to a pharmaceutical composition comprising reversible PTH conjugates. As of December 31, 2019, this patent family consists of an priority application. We expect any patents granted from this patent family to expire in February 2040.

TransCon CNP

Our patent portfolio related to TransCon CNP includes eleven patent families relating to different aspects of TransCon CNP. The first of these patent families is a composition of matter patent family directed to the particular stoichiometry of TransCon CNP and a related TransCon carrier. As of December 31, 2019, this patent family included patents granted in Europe and the United States and a patent application in Europe. We expect any patents granted in this patent family to expire in October 2024.

The second of these patent families is a composition of matter patent family directed to the TransCon linker used in TransCon CNP. As of December 31, 2019, this patent family included granted patents in the United States, Europe, the United Arab Emirates, Australia, Canada, China, Israel, Japan, Mexico and South Africa and included patent applications in Europe, the United States, Brazil, Mexico and Russia. We expect any patents granted in this family to expire in January 2029.

The third of these patent families is a composition of matter patent family directed to a broad class of TransCon CNP candidate structures. As of December 31, 2019, this patent family included patent applications in the United States, Europe, Australia, Brazil, Canada, China, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore and Thailand and a granted patent in South Africa. We expect any patents granted in this patent family to expire in January 2036.

The fourth to the ninth patent family are composition of matter patent families directed various CNP compounds having beneficial properties. As of December 31, 2019, the first one of these six patent families included patent applications in the United States, Europe, Australia, Canada, Japan, Mexico and New Zealand and a granted patent in South Africa. As of December 31, 2019, the second one included patent applications in the United States, Europe, Australia, Canada, Japan and New Zealand and a granted patent in South Africa. As of December 31, 2019, the third one included patent applications in the United States, Europe, Australia, Brazil, Canada, China, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand and Singapore and a granted patent in South Africa. As of December 31, 2019, the fourth one included patent applications in the United States, Europe, Australia, Canada, Israel and New Zealand. As of December 31, 2019, the fifth one included patent application in the United States, Europe, Australia, Brazil, Canada, China, Israel, South Korea, New Zealand and Singapore. As of December 31, 2019, the sixth one included patent applications in the United States, Europe, Australia, Canada, Israel and New Zealand. We expect any patents granted in this patent family to expire in January 2037.

The tenth patent family covers a combination therapy of TransCon CNP. As of December 31, 2019, this patent family includes patent applications in the United States, Europe, Australia, Brazil, Canada, China, Indonesia, Israel, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore, Thailand and South Africa. We expect any patents granted from this patent family to expire in September 2037.

The eleventh patent family relates to a pharmaceutical composition comprising reversible CNP conjugates. As of December 31, 2019, this patent family consists of an EP priority application. We expect any patents granted from this patent family to expire in February 2040.

Field of Oncology

As of December 31, 2019, our oncology-related patent portfolio includes eleven patent families relating to various TransCon oncology product candidates, all of which are currently in their priority year or in international phase. We expect any patents granted in these patent families to expire in or after March 2039.

TransCon Technologies

Our patent portfolio also includes patents and patent applications generally relating to our TransCon technologies, including TransCon linkers, TransCon carriers and certain soluble conjugates. We own an aggregate of 13 patent families relating to TransCon linkers, the material components of which are described above. We own an aggregate of 11 patent families relating to TransCon carriers, the material components of which are described above. Finally, we own a composition of matter patent family that is directed to soluble conjugates in which one drug molecule is connected to one TransCon carrier molecule. As of December 31, 2019, this patent family included patents in Europe and the United States and a patent application in Europe. We expect any patents granted in this patent family to expire in October 2024.

Laws and Regulations Regarding Patent Terms

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

The term of a patent that covers an FDA-approved drug or biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review

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

Government Regulation and Product Approval

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

U.S. Government Regulation

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

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

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug or biological product for each indication;

- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's or biologic's identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

We are developing an auto-injector with Philips Medisize A/S to facilitate the administration of TransCon hGH by end-users. A medical device (such as an auto-injector) marketed together with a drug or biologic is considered a combination product. 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, although submission of a Request for Designation is not mandatory. 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 often be obtained through the submission of a single marketing application. However, the FDA sometimes will require separate marketing applications for individual constituent parts of the combination product which may require additional time, effort, and information. Even when a single marketing application is required for a combination product, such as an NDA for a combination pharmaceutical and device product, both the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health will participate in the review. An applicant may 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.

Nonclinical Studies and Investigational New Drug Applications

Nonclinical studies include laboratory evaluations of product chemistry, toxicity and formulations, as well as animal studies to assess safety and efficacy. A US IND is a request for authorization from the FDA to administer an investigational pharmaceutical product to humans. A sponsor must submit the results of the nonclinical tests, together with chemistry, manufacturing & control information, and any available clinical data or literature, to the FDA as part of an IND. Some nonclinical testing may continue after the IND is submitted. An IND automatically becomes effective and a clinical trial proposed in the IND may begin 30 days after the FDA receives the IND, unless during this 30-day waiting period, the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the sponsor must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. The FDA may impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical Trials

Clinical trials involve the administration of the investigational pharmaceutical product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND and to other Health Authorities and Ethics Committees outside the US as part of Clinical Trial Applications. 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 (NIH), for public dissemination on their www.clinicaltrials.gov website.

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

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

Phase 1, phase 2 and phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA, other Health Authorities, 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 or Ethics Committee can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

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

Marketing Approval in the U.S.

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval or licensure to market the product for one or more indications. In most cases, the submission of an NDA or BLA is subject to a substantial

application user fee. Under the Prescription Drug User Fee Act guidelines that are currently in effect, the FDA has a goal of 10 months from the date of "filing" of a standard NDA for a new molecular entity or original BLA to review and act on the submission. This review typically takes 12 months from the date the NDA or BLA is submitted to the FDA because the FDA has sixty days from receipt to decide whether an application is accepted for filing, as described below.

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

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

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

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

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

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

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

After evaluating the NDA or BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA or BLA identified by the FDA and may require additional clinical data, such as an additional pivotal phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application (without prejudice to a subsequent submission). Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications.

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

Post-Approval Requirements

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

There also are continuing, annual program fee requirements for certain approved prescription drug or biologic products. The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

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

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

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

Other potential consequences include, among other things:

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

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

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

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product in the United States. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different product for the same disease or condition or the same product for a different disease or condition.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor with orphan drug designation obtains approval before we do of the same product, as defined by the FDA, for the same orphan indication we are seeking, or if our product candidate is determined to be contained within the scope of the competitor’s product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity.

Pediatric Exclusivity

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

Biosimilars and Exclusivity

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

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

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

Foreign Regulation

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

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

Centralized Procedure in the European Union

The centralized procedure provides for the grant of a single marketing authorization from the European Commission following a favorable opinion by the Committee for Medicinal Products for Human Use, or the CHMP, of the EMA that is valid in all European Union member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products) and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not authorized in the EEA before May 20, 2004, or that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Within 15 days of the adoption, the EMA will forward its opinion to the European Commission to start the decision-making phase. Within 15 days a draft implementing decision is sent by the Commission to the Standing Committee on Medicinal Products for Human Use, allowing for its scrutiny by EU countries. These have fifteen days to return their linguistic comments, and 22 days for substantial ones. Once a favorable opinion is reached, the draft decision is adopted via an empowerment procedure. The adoption of the decision should take place within 67 days of the opinion of the EMA. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding clock stops.

National Authorization Procedures in the European Union

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

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

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

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

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

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

Other Healthcare Laws

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

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing,

purchases, or recommendations may be subject to scrutiny if they do not meet the strict requirements of a statutory or regulatory exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances in light of the prohibitions in the statute. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The majority of states also have anti-kickback laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. As with the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA imposed, among other things, new annual reporting requirements for covered manufacturers for certain payments and "transfers of value" provided to physicians, certain other healthcare professionals beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in significant civil monetary penalties of up to an aggregate of 150,000 per annual report and up to a maximum of $1,150,000 in combined penalties per year for "knowing failures." Covered manufacturers must submit reports by the 90th day of each subsequent calendar year. In addition, certain states require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices, and/or tracking and reporting of marketing expenditures and pricing information as well as gifts, compensation and other remuneration or items of value provided to physicians and other healthcare professionals and entities.

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.

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

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drugs, medical devices and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. Many countries outside the U.S., including the European Union ("EU") member states, established complex and lengthy procedures to obtain price approvals, coverage and reimbursement. These procedures vary from country to country but are commonly initiated after grant of the related marketing authorization. Many EU member states review periodically their decisions concerning the pricing and reimbursement of medicinal products. The outcome of these reviews cannot be predicted and could have adverse effects on the pricing and reimbursement of our medicinal products in the EU member states.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in 2010, the ACA and related legislation were enacted, which, among other things, (i) increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, (ii) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, (iii) extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans, (iv) imposed mandatory discounts for certain Medicare Part D beneficiaries, (v) subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs and (vi) imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices (which was subsequently repealed in December 2019).

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the Tax Cuts and Jobs Act, enacted on December 22, 2017, removes penalties for not complying with the ACA's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that because the individual mandate is a critical and inseverable feature of the ACA, the remaining provisions of the ACA were invalid as well. Upon appeal, the U.S. Court of Appeals for the Fifth Circuit affirmed that the individual mandate was unconstitutional but remanded the case back to the U.S. District Court to determine what portions of the ACA, if any, might continue to be valid. On January 21, 2020, the U.S. Supreme Court declined a motion by the U.S. House of Representatives and others seeking expedited review of the case. It is unclear how these decisions, subsequent appeals and other efforts to challenge, repeal or replace the ACA will impact the law.

On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. These measures include reductions in Medicare payments to providers, capped at 2% per fiscal year, which went into effect on April 1, 2013. These reductions, extended by subsequent legislation, will stay in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced certain Medicare payments to several types of providers, including hospitals. The legislation also increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including through constraints on reimbursement, imposition of mandatory discounts, restrictions on access to certain products, transparency measures, and programs for importation from other countries or bulk purchasing.

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

In the EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems, parallel distribution and parallel trade. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced countries. Reductions in the pricing of our medicinal products in one EU member state could affect the price in other EU member states and, thus, have a negative impact on our financial results.

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

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

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

Data Privacy and Security

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

In the U.S., HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, effective January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context.

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

C. Organizational Structure

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

D. Property, Plant and Equipment

Our headquarters are located at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark, where we lease 5,477 square meters of office space. The lease can be terminated by us at the earliest on July 1, 2024 for 1,223 square meters and on July 1, 2026 for 4,254 square meters. In addition, we have expanded the lease with 1,862 square meters of office space, commencing on January 1, 2019 which can be terminated by us at the earliest on July 1, 2026. Unless terminated within the early termination period or if the leases are not prolonged, the leases expire on July 1, 2029.

Further, we have entered into an additional lease of 1,567 square meters of office space at Tuborg Boulevard 5, DK-2900 Hellerup, Denmark. The lease can be terminated by us at the earliest on November 30, 2022. Unless terminated within the early termination period or if the lease is not prolonged, the lease expires on November 30, 2028.

We maintain research facilities in Heidelberg, Germany, where we lease 2,614 square meters of office and laboratory space. For one site, comprising 2,134 square meters, this lease is continuously extended for 24 months periods, and accordingly, if not terminated by either us or lessor, no later than January 31, 2020, the lease expires on January 31, 2023. The other site, which commenced on July 1, 2019, expires on December 31, 2021.

In addition, we entered an office lease in Berlin, comprising 165 square meters, commencing on January 15, 2019. This lease expires on May 31, 2020, but may, subject to certain conditions, be extended for two years at our option.

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

In addition, we are in the process of constructing a research laboratory for our oncology therapeutic areas, and in this connection we have leased a site of 3,681 square meters in Redwood City, California, commencing on November 1, 2019. This lease expires on April 30, 2030, however, subject to certain conditions, may be extended for five years at our option.

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 “Special Note Regarding Forward-Looking Statements” sections and elsewhere in this annual report.

A. Operating Results

Overview

We are applying our innovative TransCon technologies to build a leading, fully integrated biopharmaceutical company and develop a pipeline of product candidates with potential best in class profiles to address unmet medical needs. We have created a portfolio of potential best in class rare disease endocrinology product candidates to address unmet medical needs by utilizing our TransCon technologies with clinically validated parent drugs. We currently have three product candidates in clinical development in rare endocrine diseases and we are advancing multiple preclinical candidates in oncology, our second therapeutic area of focus. We are also working to apply our TransCon technology platform in additional therapeutic areas to address unmet patient needs.

Our most advanced investigational product candidate, TransCon hGH, is in development as a once-weekly long-acting prodrug of recombinant human growth hormone, also referred to as somatropin or hGH, as a potential treatment for pediatric and adult growth hormone deficiency, or GHD. Our phase 3 pediatric program for TransCon hGH consists of the heiGHt, fliGHt and enliGHten Trials. Our results from the pivotal, phase 3 heiGHt Trial demonstrated a statistically significant increase in annualized height velocity, or AHV, compared to daily hGH at 52 weeks, and showed a safety profile comparable to that of daily hGH in pediatric subjects who were treatment-naïve.

Nearly all subjects who completed the heiGHt or fliGHt Trials have enrolled in the open-label extension study, or the enliGHten Trial, which is designed to provide long-term safety data to support the planned regulatory filings for TransCon hGH. We initiated the enliGHten Trial in 2017 as the first subjects began to roll over from the heiGHt Trial, and we have enrolled approximately 300 subjects, which we believe will form a safety database consistent with input received from regulatory authorities.

In September 2019, we completed the last subject visit forming the two-year follow up for the TransCon hGH phase 3 program in pediatric GHD. These data will form the safety database to support submission of a Biologics License Application, or BLA, to the U.S. Food and Drug Administration, or the FDA, for TransCon hGH to treat pediatric GHD, which we expect to submit in the second quarter of 2020, as well as submission of a Marketing Authorisation Application to the European Medicines Agency expected in the fourth quarter of 2020.

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

We believe that TransCon hGH, if approved, may offer a once-weekly therapy for pediatric and adult GHD with the potential to improve outcomes compared to currently approved daily hGH. If approved, we believe TransCon hGH may reduce the burden of daily treatment by requiring significantly fewer injections, which we believe may improve compliance and treatment outcomes. After receiving feedback from the FDA, we have filed an IND amendment to initiate a global, phase 3 trial in subjects with adult GHD and we intend to pursue other indications for TransCon hGH consistent with our strategy to create sustainable growth.

We are also using our TransCon technology platform to develop TransCon PTH, an investigational once-daily long-acting prodrug of parathyroid hormone, or PTH, as a potential treatment for adult hypoparathyroidism, a rare endocrine disorder of calcium and phosphate metabolism. We completed a phase 1 trial in healthy subjects in 2018, the results of which were consistent with our target product profile for TransCon PTH as a “true” replacement therapy. In this trial, TransCon PTH showed the predicted pharmacokinetic and pharmacodynamic response, suggesting the ability to normalize serum and urinary calcium levels in patients with hypoparathyroidism.

Our ongoing phase 2 PaTH Forward Trial is evaluating the safety, tolerability and efficacy of three fixed doses of TransCon PTH using a ready-to-use prefilled pen device. The goal of PaTH Forward is to identify a starting dose (15, 18, or 21 µg per day) for a pivotal phase 3 trial, establish a titration regimen for complete withdrawal of standard of care (i.e., active vitamin D and calcium supplements), and evaluate TransCon PTH control of serum and urinary calcium. In February 2020, we completed enrollment of the trial with 59 subjects and we expect to report top-line data from the one-month blinded portion of the PaTH Forward Trial in mid-April 2020. Following evaluation of Phase 2 data from the PaTH Forward Trial, we expect and plan to initiate a global phase 3 program for TransCon PTH in the fourth quarter of 2020, including trial sites in the United States, Canada, Europe and Asia-Pacific, including Japan.

In June 2018, we were granted Orphan Drug Designation, or ODD, by the FDA for TransCon PTH. ODD is provided to drugs that are intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. We believe TransCon PTH, if approved, may provide patients suffering from hypoparathyroidism with a PTH replacement therapy that is designed to address both the short-term symptoms and long-term complications of the disease.

We are also developing TransCon CNP, an investigational long-acting prodrug of C-type natriuretic peptide, or CNP, as a potential therapeutic option for achondroplasia, the most common form of dwarfism. TransCon CNP is designed to provide continuous CNP exposure with the goal of optimizing efficacy with a safe and convenient once-weekly dose. Currently, there are no medical therapies for achondroplasia approved by the FDA. In November 2018, we reported preliminary results from a phase 1 trial in healthy adult subjects, which supported our target product profile for TransCon CNP. In February 2019, we were granted ODD by the FDA for TransCon CNP. Following successful submission of an IND application in July 2019, we initiated the phase 2 ACcomplisH Trial to evaluate safety and efficacy of TransCon CNP in children (ages 2-10 years) with achondroplasia. The company continues to work towards escalating sequential dose cohorts throughout the year, while ensuring the safety of subjects during the current pandemic and access to physicians for future monitoring visits. Our goal is to develop TransCon CNP as a safe and effective therapeutic option for achondroplasia and potentially other related growth disorders.

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

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

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

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

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

We had a net loss of €218.0 million for the year ended December 31, 2019 compared to a net loss of €130.1 million for the year ended December 31, 2018, and a net loss of €123.9 million for the year ended December 31, 2017. Our total equity was €597.1 million as of December 31, 2019 compared to €280.1 million as of December 31, 2018. We have not generated royalties or revenues from product sales, and do not expect to generate royalties or revenues from product sales prior to regulatory approval of any of our product candidates.

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

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

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

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, including delivery of clinical supply material, 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 and the material we deliver.

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

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

Research and Development Costs

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

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

Government grants are recognized when there is reasonable assurance that the conditions underlying the grant have been met and that the grant will be received. We did not receive any government grants in 2019, 2018 or 2017. 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, 2019, we incurred direct and indirect research and development costs of €105.7 million and €85.9 million, respectively, compared to €89.5 million and €50.8 million, respectively, for the year ended December 31, 2018 and €67.0 million and €32.6 million, respectively, for the year ended December 31, 2017.

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

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

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

- the scope, rate of progress and expense of our research and development activities;
- clinical trial and early-stage results;
- the terms and timing of regulatory approvals;

- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the ability to market, commercialize and achieve market acceptance for our product candidates.

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

General and Administrative Expenses

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

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

Finance Income and Finance Expenses

We do not hold any interest-bearing debt. As such, finance income and finance expenses consist primarily of interest income, interest expenses recognized for lease liabilities, 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, 2019, 2018 and 2017:

	Year Ended December 31,		
	2019 (EUR'000)	2018 (EUR'000)	2017 (EUR'000)
Revenue	13,375	10,581	1,530
Research and development costs	(191,621)	(140,281)	(99,589)
General and administrative expenses	(48,473)	(25,057)	(13,482)
Operating profit / (loss)	**(226,719)**	**(154,757)**	**(111,541)**
Share of profit / (loss) in associate	(8,113)	(321)	—
Finance income	17,803	24,714	923
Finance expenses	(1,221)	(127)	(13,756)
Profit / (loss) before tax	**(218,250)**	**(130,491)**	**(124,374)**
Tax on profit / (loss) for the year	234	394	477
Net profit / (loss) for the year	**(218,016)**	**(130,097)**	**(123,897)**

Revenue

The following table summarizes our revenue for the years ended December 31, 2019, 2018 and 2017:

	Year Ended December 31,		
	2019 (EUR'000)	2018 (EUR'000)	2017 (EUR'000)
Revenue from the rendering of services (recognized over time)	9,919	1,215	1,530
Sale of clinical supply (recognized at a point in time)	804	—	—
"Right-to-use" licenses (recognized at a point in time)	2,652	9,366	—
Total revenue	**13,375**	**10,581**	**1,530**

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

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

As of December 31, 2019, we had deferred income of €0.9 million under the agreement with Visen, compared to deferred income from Visen and other collaboration agreements of €6.9 million and €0 million as of December 31, 2018 and 2017, respectively. This deferred income will be recognized as revenue as we advance the projects that are subject to our collaborations with Visen.

Research and Development Costs

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

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

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

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

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

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

General and Administrative Expenses

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

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

Net Profit / (Loss) in Associate

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

Finance Income and Finance Expenses

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

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

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

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

Tax on Profit / (Loss) for the Year

Tax for the year ended December 31, 2019 was a net tax credit of €0.2 million, compared to a net tax credit of €0.4 million for the year ended December 31, 2018. 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, 2019, the jointly taxed Danish entities had a tax loss, and accordingly were entitled to a tax refund of approximately €0.7 million. The tax for the year ended December 31, 2019 further comprised a tax provision of €0.4 million related to our subsidiary in Germany and a net tax provision of €0.1 million related to our subsidiary in the United States.

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

At December 31, 2019, 2018 and 2017, we had net deferred tax assets of €128.9 million, €78.5 million, and €52.7 million, respectively, which were not recognized in the consolidated statement of financial position due to uncertainties relating to the future utilization. The increase in the unrecognized deferred tax asset can primarily be attributed to an increase in tax losses carried forward. The deferred tax asset can be carried forward without timing limitations. For tax losses carried forward, certain limitations exist for amounts to be utilized each year.

Quantitative and Qualitative Disclosures about Market Risk

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

Foreign Currency Risk

We are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the U.S. Dollar, the British Pound and the Danish Krone. We have received payments in U.S. Dollars under our collaborations and the proceeds from our Series D financing in November 2014, our IPO in February 2015 and our follow-on offerings in October and November 2016, in September and October 2017, in February 2018 and in March 2019 were in U.S. dollars. We seek to minimize our exchange rate risk by maintaining cash positions in the currencies in which we expect to incur the majority of our future expenses and we make payments from those positions. As required under IFRS, we perform an analysis and report on our foreign currency exposure on an annual basis. At December 31, 2019, the net carrying amount of our monetary assets and liabilities was €526.2 million, and we held €451.5 million denominated in U.S. Dollars, primarily related to the proceeds from the follow-on offering completed in March 2019.

A sensitivity analysis of our exposure to the U.S. Dollar based on outstanding foreign currency denominated monetary items as of December 31, 2019 shows that a strengthening of the U.S. Dollar against the Euro by 10% would increase net profit or loss and equity by €47.8 million. A 10% weakening of the U.S. Dollar against the Euro would decrease net profit or loss and equity by a similar amount.

Interest Rate Risk

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

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

Credit Risk

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

Liquidity Risk

We manage our liquidity risk by maintaining adequate cash reserves and banking facilities, and by continuously monitoring our cash forecasts and actual cash flows, and by matching the maturity profiles of financial assets and liabilities. Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2019 are sufficient to meet our projected cash requirements for at least 12 months from the date of this annual report.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with IFRS as issued by the IASB. A description of our accounting policies is provided in the Accounting Policies section of the audited consolidated financial statements as of and for the years ended December 31, 2019, 2018 and 2017 included elsewhere in this annual report. In the application of our accounting policies, we are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. In some instances, we could have reasonably used different accounting estimates, and in other instances changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ significantly from the estimates we have made. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial conditions, results of operations and cash flows will be affected.

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

Critical Accounting Policies

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

Revenue Recognition

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

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

Critical judgments relating to specific revenue transactions are described below.

License Agreements

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

Identifying Performance Obligations and Allocating Transaction Price

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

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

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

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

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

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

Share-Based Payment

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

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

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

Share-based payment was €37.5 million, €19.7 million and €9.7 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Internally Generated Intangible Assets

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

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

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

Joint Arrangements / Collaboration Agreements

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

Key Sources of Estimation Uncertainty

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

Revenue Recognition - Allocation of Transaction Price to Performance Obligations

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

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

Impairment of Goodwill

Determining whether goodwill is impaired requires an estimation of the recoverable amount, being the higher of fair value less costs of disposal or value in use, of the cash-generating units to which goodwill has been allocated. The Company is determined to be a single cash-generating unit. Accordingly, the recoverable amount is determined based on an estimation of the Company's fair value less costs of disposal. We have determined the fair value of goodwill after taking into account the market value of our ADSs representing the enterprise value of the group enterprise as of the reporting date. No impairment loss has been recognized in 2019, 2018 or 2017. The carrying amount of goodwill as of December 31, 2019 and 2018 was €3.5 million.

Recognition of Accruals and Prepayments for Development, 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 reporting date to determine the stage of completion compared to the invoices received and recognized accruals for any additional costs or prepayments for any invoiced costs in excess of the stage of completion. As of December 31, 2019, the consolidated statement of financial position included prepaid project costs of €5.8 million and accrued project costs of €10.5 million, compared to €11.4 million and €9.1 million, respectively, as of December 31, 2018.

Useful Lives of Property, Plant and Equipment

We review the estimated useful lives of property, plant and equipment at the end of each reporting period. We have concluded that the useful lives applied for 2019, 2018 and 2017 are appropriate.

Leases

In connection with adopting IFRS 16, the following are assessed as key assumptions concerning estimation uncertainty that have a significant risk of causing a material adjustment to the carrying amount of right-to-use assets and/or lease liabilities within the next financial year.

Lease Term

Certain lease arrangements provide us with a contractual right (not obligation) to either extend the lease after the initial term, or to terminate the lease within the enforceable lease term, i.e., periods where lessor cannot terminate the lease. Those options cover periods in the range from 1-6 years in addition to the non-cancellable periods. Based on our assessment at December 31, 2019, the lease terms reflect only the non-cancellable periods.

Incremental Borrowing Rate

Lease payments are discounted over the non-cancelable periods, applying each contract's incremental borrowing rate. In determining incremental borrowing rates, we have considered the contracts' specific payment profiles and relevant currencies, and applied a corresponding risk-free interest rate, credit spread, and an asset specific adjustment, if applicable. The incremental borrowing rates applied are 2.25-2.5% and 4.25-5.0% for lease contracts denominated in EUR or Danish Kroner, and U.S. Dollars, respectively.

B. Liquidity and Capital Resources

As of December 31, 2019, we had cash and cash equivalents totaling €598.1 million. We have funded our operations primarily through issuance of our preference shares, ordinary shares and convertible debt securities and payments to us under our collaboration agreements. Our expenditures are primarily related to research and development activities and general and administrative activities to support research and development. We do not have any debt to third parties.

On February 2, 2015, we announced the closing of our initial public offering, with net proceeds of $111.5 million (or €101.4 million) after deducting underwriting commissions and offering expenses. On October 24, 2016, we completed a follow-on public offering of ADSs, with net proceeds of $111.7 million (or €102.6 million), after deducting underwriters' commissions and offering expenses. On November 2, 2016, we completed the partial exercise of the underwriters' option to purchase additional ADSs, with net proceeds of $15.4 million (or €14.0 million) after deducting underwriters' commissions and offering expenses. On September 29, 2017, we completed a follow-on public offering of ADSs, with net proceeds of $126.2 million (or €106.9 million), after deducting underwriters' commissions and offering expenses. On October 5, 2017, we completed the exercise in full of the underwriters' option to purchase additional ADSs, with net proceeds of $19.0 million (or €16.2 million), after deducting underwriters' commissions and offering expenses. On February 21, 2018, we completed a follow-on public offering of ADSs, with net proceeds of $210.8 million (or €171.2 million), after deducting underwriters' commissions and estimated offering expenses. On February 22, 2018, we completed the exercise in full of the underwriters' option to purchase additional ADSs, with net proceeds of $31.7 million (or €27.4 million) after deducting underwriters' commissions and offering expenses. On March 5, 2019, we completed a follow-on public offering of ADSs, with net proceeds of $468.9 million (or €417.9 million), after deducting underwriters' commissions and offering expenses. On March 14, 2019, we completed the exercise in full of the underwriters' option to purchase additional ADSs, with net proceeds of $70.5 million (or €62.4 million), after deducting underwriters' commissions and offering expenses. Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2019 will be sufficient to meet our projected cash requirements for at least 12 months from the date of this annual report. However, our operating plan may change as

a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including, but not limited to:

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

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

Since our inception, as of December 31, 2019, we have funded our operations through the sale of €1,191.4 million of our preference shares, ordinary shares and convertible debt securities, including our IPO, follow-on offerings and exercise of warrants, and we have received aggregate gross proceeds of approximately €76.5 million from collaboration partners for up-front technology licensing fees, assignment of certain intellectual property rights and for services rendered under those agreements.

The following table summarizes our cash flows for the years ended December 31, 2019, 2018 and 2017:

	Year Ended December 31,		
	2019 (EUR'000)	2018 (EUR'000)	2017 (EUR'000)
Cash flows from/(used in) operating activities	(175,936)	(138,802)	(95,099)
Cash flows from/(used in) investing activities	(5,159)	(2,648)	(941)
Cash flows from/(used in) financing activities	493,593	203,267	124,721
Net increase in cash and cash equivalents	**312,498**	**61,817**	**28,681**

Cash flows from/(used in) Operating Activities

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

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

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

Cash Flows used in Investing Activities

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

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

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

Cash Flows from / (used in) Financing Activities

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

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

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

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, 2019:

	Payments Due by Period				
	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years	Total
	(EUR’000)				
Contractual Obligations:					
Lease Obligations(1)	6,191	11,153	8,603	17,605	43,552
Construction of leasehold improvements	8,523	—	—	—	8,523
Total contractual obligations	14,714	11,153	8,603	17,605	52,075

(1) Lease Obligations primarily comprise leased offices in Denmark and the United States, and leased offices and laboratories in Germany. In accordance with IFRS 16, “Leases”, lease obligations for other than those relating to short-term leases and leases of low value assets have been recognized in the balance sheet as of December 31, 2019 as right-of-us assets included in property, plant and equipment, and as lease liabilities.

With certain suppliers, the Company has agreed minimum commitments related to manufacturing of product supply, subject to continuous negotiation and adjustments according to the individual contractual terms and conditions. Delivery of product supply is recognized when the Company obtains control of the goods.

Of other contractual commitments, the Company has entered into short term leases and leases of low value equipment and service contracts of various lengths in respect of research and development, IT- and facility related services. In addition, the Company’s lease activities establish contractual commitments in relation to non-lease components which consists of utilities, maintenance, levies, and other services. Costs relating to those commitments are recognized as services are received.

G. Safe harbor

See “Special Note Regarding Forward-Looking Statements”.

Item 6 Directors, Senior Management and Employees

A. Directors and Senior Management

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

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

Board of Directors

The following table sets forth information with respect to each of our current board members and their respective ages as of December 31, 2019. Our board of directors is divided into two classes for purposes of election. One class is elected at each annual meeting of shareholders to serve for a two-year term. Our board of directors currently consists of seven members. All board members are eligible for re-election once their term expires.

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

Name of Board Member	Age	Position(s)	Term Expires
Michael Wolff Jensen, L.L.M.	48	Chairman and Senior Vice President, Chief Legal Officer	2021
Lisa Bright	52	Board Member	2021
Albert Cha, M.D., Ph.D.	47	Board Member	2020
James I. Healy, M.D., Ph.D.	54	Board Member	2021
Jan Møller Mikkelsen	60	President, Chief Executive Officer, Board Member and Executive Director	2021
Birgitte Volck, M.D., Ph.D.	57	Board Member	2020
Lars Holtug	61	Board Member	2020

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

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

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

James I. Healy, M.D., Ph.D. has served as a member of our board of directors since November 2014. Dr. Healy has been a General Partner of Sofinnova Investments, Inc. (formerly Sofinnova Ventures), a venture capital firm, since June 2000. Prior to June 2000, Dr. Healy held various positions at Sanderling Ventures, Bayer Healthcare Pharmaceuticals (as successor to Miles Laboratories) and ISTA Pharmaceuticals, Inc. Dr. Healy is currently on the board of directors of Ascendis Pharma A/S (Nasdaq: ASND), Coherus BioSciences, Inc. (Nasdaq: CHRS), NuCana plc (Nasdaq: NCNA), Karuna Therapeutics, Inc. (Nasdaq: KRTX), Natera, Inc. (Nasdaq: NTRA), ObsEva SA (Nasdaq: OBSV), Y-mAbs Therapeutics, Inc. (Nasdaq: YMAB) and two private companies. Previously, he served as a board member of Amarin Corporation, Auris Medical Holding AG, Edge Therapeutics, Inc., Hyperion Therapeutics, Inc., InterMune, Inc., Iterum Therapeutics plc, Anthera Pharmaceuticals, Inc., Durata Therapeutics, Inc., CoTherix, Inc., Movetis NV and several private companies. In 2011, Dr. Healy won the IBF Risk Innovator Award and was named as one of the industry's top leading Life Science investors in 2013 by Forbes Magazine. 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. He was previously a Director on the Board of the National Venture Capital Association (NVCA) and the Board of the Biotechnology Industry Organization (BIO).

Birgitte Volck, M.D., Ph.D. has served as a member of our board of directors since May 2016. Dr. Volck has served as the President, Head of Research and Development at AVROBIO Inc., a phase 2 clinical stage gene therapy company since December 2018. From June 2016 to August 2018, Dr. Volck served as head of Research and Development, Rare Diseases for GlaxoSmithKline plc. From August 2012 to 2016, Dr. Volck served as the Chief Medical Officer and Senior Vice President of Development at Swedish Orphan Biovitrum AB, a biopharmaceutical company. From 2007 to July 2012, Dr. Volck held various positions at Amgen Inc., a biopharmaceutical company, including Executive Development Director, Bone, Neuroscience & Inflammation. Prior to Amgen, from 2004 to 2007, Dr. Volck served as Nordic Medical Director and Project Director at Genzyme A/S, a biotechnology company. From 2001 to 2004, Dr. Volck served as Head of Clinical Development and Medical Affairs at Pharmexa, a biotechnology company. From June 2019, Dr. Volck serves as a non-executive director at Soleno Therapeutics. From May 2017 to June 2018, Dr. Volck served as a non-executive director for Wilson Therapeutics AB, a biotechnology company. From May 2016 to April 2019, Dr. Volck has served as a director for TFS International, a clinical research organization. Dr. Volck received her M.D. and Ph.D. degrees from Copenhagen University, Denmark.

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

Senior Management and Executive Board

The following table sets forth information with respect to each of the members of our senior management, their respective ages and their positions as of December 31, 2019. In addition to serving as members of our senior management, Mr. Mikkelsen and Mr. Smith currently serve as the members of our executive board. The business address of these members of our senior management is our registered office address at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark.

Name	Age	Position(s)
Jan Møller Mikkelsen	60	President, Chief Executive Officer, Board Member and Executive Director
Flemming Steen Jensen	58	Senior Vice President, Product Supply
Michael Wolff Jensen, L.L.M.	48	Chairman and Senior Vice President, Chief Legal Officer
Peter Rasmussen	51	Vice President, Finance and Principal Accounting Officer
Scott T. Smith	46	Senior Vice President, Chief Financial Officer
Lotte Sønderbjerg	58	Senior Vice President, Chief Administrative Officer
Kennett Sprogøe, Ph.D.	41	Senior Vice President, Head of Innovation and Research

Thomas A. Larson	58	Senior Vice President, Chief Commercial Officer
Juha Punnonen, M.D., Ph.D.	54	Senior Vice President, Head of Oncology
Jens Sigurd Okkels	59	Senior Vice President, Product Development
Vibeke Miller Breinholt, Ph.D.	53	Senior Vice President, Nonclinical Development and Bioanalysis
Dana Pizzuti, M.D.	64	Senior Vice President, Development Operations

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

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

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

Michael Wolff Jensen, L.L.M. has served as Chairman of our board of directors since January 2008 and as our Senior Vice President, Chief Legal Officer 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, 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 XSpray Pharma AB, a publicly traded biotechnology company. Mr. Jensen was also elected as chairman of a Danish private sports manufacturing goods company in November 2016. Mr. Jensen received an L.L.M. degree from the University of Copenhagen.

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

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

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

Kennett Sprogøe, Ph.D. has held positions of increasing responsibility at Ascendis Pharma since December 2007, including serving as our Senior Vice President, Head of Innovation and Research since 2019, our Senior Vice President, Product Innovation since January 2016, our Vice President, Product Innovation from June 2014 to December 2015 and our Director, Portfolio Development from November 2012 to May 2014. Prior to joining Ascendis Pharma, Dr. Sprogøe conducted research at the University of Copenhagen, where he applied novel hyphenated screening technologies to expedite discovery of drug leads from natural sources. Dr. Sprogøe holds a Ph.D. in Natural Products Chemistry from the University of Copenhagen and a M.Sc. in Pharmacy from the Danish University of Pharmaceutical Sciences.

Thomas A. Larson has served as our Senior Vice President and Chief Commercial Officer since April 2019. Previously, Mr. Larson was Vice President and Chief Commercial Officer at Mitsubishi Tanabe Pharma America, a pharmaceutical company, since 2016. At Mitsubishi, he established the U.S. commercial organization and successfully launched the company's first U.S. pharmaceutical product, Radicava®, the first amyotrophic lateral sclerosis (ALS) therapy approved in the U.S. in over 20 years. From 2013 to 2016, Mr. Larson was a member of the commercial team for Marathon Pharmaceuticals, a biopharmaceuticals company, where he helped build the commercial infrastructure. Prior to Marathon, he worked for Boehringer-lngelheim, a pharmaceutical company, and Johnson & Johnson, a consumer manufacturing company, where he launched multiple products and oversaw various sales and marketing activities focused on hospital and specialty markets. Mr. Larson began his career at Abbott Laboratories, a healthcare company, in 1985, where he worked in research and development, sales, market access and marketing roles of increasing responsibility over his 18-year tenure, including leadership positions in the commercial organization supporting orphan drug, hospital, biologics and specialty product launches. Mr. Larson holds a Bachelor of Science in Biochemistry from Northern Michigan University.

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

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

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

Dana Pizzuti, M.D. has served as our Senior Vice President of Development Operations since January 2020 and Vice President of Global Regulatory Affairs since July 2019. Dr. Pizzuti has more than 30 years of pharmaceutical industry experience in clinical development, pharmacovigilance, medical and regulatory Affairs. Prior to joining Ascendis Pharma, Dr. Pizzuti served as Senior Vice President of Regulatory Affairs, Quality and Pharmacovigilance at Theravance Biopharma, Inc., a biotechnology company, from March 2019 to July 2019 and served as Senior Vice President of Regulatory Affairs and Quality at Rigel Pharmaceuticals, a biotechnology company, from June 2017 to March 2019. Prior to Rigel, Dr. Pizzuti served as Vice President of Regulatory Affairs at Gilead Sciences, a pharmaceutical company, from March 2007 to June 2017, where she directly supervised a global regulatory department of more than 500 individuals in 33 countries and was responsible for obtaining marketing authorizations for 15 new drugs in global markets. Prior to Gilead, she served as Vice President of Global Regulatory Affairs for West Coast Pharmaceuticals at Johnson and Johnson and Vice President of Global Pharmacovigilance and Labeling at Bristol-Myers Squibb. For 10 years, she held positions of increasing responsibility in Medical Affairs at Abbott Laboratories, ending her tenure there as Vice President of Global Medical Affairs for the Pharmaceutical Products Division and Abbott International. Dr. Pizzuti began her career in industry at Hoffmann-La Roche. She received her M.D. from New York University and a B.S. in Biology (cum laude) from Yale University.

B. Compensation

Compensation of Members of Our Board of Directors and Senior Management

During 2019, Dr. Cha received board fees in the amount of €40,218 for his membership on our board and €16,981 for his tenure on the remuneration committee and the nominating and corporate governance committee, Dr. Healy received €40,218 for his membership on our board and €17,874 for his tenure on the nominating and corporate governance committee and the audit committee, Ms. Volck received €33,720 for her membership on our board and €4,215 for her tenure on the nominating and corporate governance committee, Ms. Bright received €37,935 for her membership on our board and €13,910 for her tenure on the audit committee and the remuneration committee, and Mr. Holtug received €37,935 for his membership on our board and €22,340 for his tenure on the audit committee and the remuneration committee. Neither Messrs. Michael Wolff Jensen nor Mikkelsen received any compensation in respect of their service on the board. Their compensation under our senior management compensation program is described below.

On December 10, 2019, Dr. Cha, Dr. Healy, Dr. Volck, Ms. Bright and Mr. Holtug were each granted 7,500 warrants, in each case with an exercise price per share of $108.00 (€97.4993) and an expiration date on December 10, 2029. The aggregate grant date fair value of the warrants granted to our board members in 2019 for their services as board members was €1,655,990.

The primary objective of our senior management's compensation program is to attract, motivate, reward and retain the managerial talent needed to achieve our business objectives. In addition, the compensation program is intended to compensate all employees at competitive market rates, while recognizing extraordinary accomplishments. Compensation arrangements for our senior management have been designed to align a portion of their compensation

with the achievement of our business objectives and growth strategy. Bonus payments for our senior management are determined with respect to a given year based on quantitative and qualitative goals set for our company as a whole, as well as on an individual basis. Once the results of the year are known, bonus payments are determined at the discretion of our board and, with respect to senior management reporting to the CEO, in light of recommendations made by the CEO.

The aggregate compensation paid to our senior management who were employed by our company during 2019, consisting of Messrs. Jan Møller Mikkelsen, Scott T. Smith, Michael Wolff Jensen, Peter Rasmussen, Flemming Steen Jensen and Thomas A. Larson, Ms. Sønderbjerg and Drs. Leff, Sprogøe, Okkels, and Punnonen, for the fiscal year ended December 31, 2019 was approximately €21.7 million. This amount consists of: (i) short-term employee benefits including salary and other in-kind benefits of approximately €3.8 million, (ii) bonuses of €2.0 million, (iii) share-based payments of approximately €15.9 million, and (iv) post-employment and other benefits of €0.3 million. Share-based payments reflect the 2019 expenses of warrants granted in or before 2019. During 2019, the board made the following warrant grants to members of our senior management who were employed by our company during 2019:

Name	Grant Date	Shares Subject to Awards Granted	Award Exercise Price(s)		Award Expiration Date
Sigurd Okkels	April 9, 2019	90,000	$119.13	(€105.64)	April 9, 2029
Sigurd Okkels	December 10, 2019	27,000	$108.00	(€97.4993)	December 10, 2029
Dana Pizzuti	August 13, 2019	20,000	$114.96	(€102.44)	August 13, 2029
Thomas A. Larson	December 10, 2019	27,000	$108.00	(€97.4993)	December 10, 2029
Juha Punnonen	December 10, 2019	27,000	$108.00	(€97.4993)	December 10, 2029
Jan Møller Mikkelsen	December 10, 2019	120,000	$108.00	(€97.4993)	December 10, 2029
Scott T. Smith	December 10, 2019	27,000	$108.00	(€97.4993)	December 10, 2029
Michael Wolff Jensen	December 10, 2019	27,000	$108.00	(€97.4993)	December 10, 2029
Lotte Sønderbjerg	December 10, 2018	27,000	$108.00	(€97.4993)	December 10, 2029
Flemming Steen Jensen	December 10, 2019	27,000	$108.00	(€97.4993)	December 10, 2029
Kennett Sprogøe	December 10, 2019	27,000	$108.00	(€97.4993)	December 10, 2029
Peter Rasmussen	December 10, 2019	6,000	$108.00	(€97.4993)	December 10, 2029
Vibeke Miller Breinholt	December 10, 2019	6,000	$108.00	(€97.4993)	December 10, 2029

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, 2019 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 and Ms. Sønderbjerg contain a termination notice period of three months for a termination by the employee and six months for a termination by us (except that in the case of Ms. Sønderbjerg, the notice period may be no less than the notice required pursuant to the rules of the Danish Salaried Employees Act with the addition of two months). The agreement with Mr. 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. Sprogøe contains a termination notice period of one month for a termination by the employee and six months for a termination by us. The agreements with Drs. Okkels and Breinholt provide that the notice period may be no less than the notice required pursuant to the rules of the

Danish Salaried Employees Act, which is at any time mutually extended by both parties with two months notice to the end of a month, provided that the executive may terminate with one month's notice in the case of certain conditions related to sickness. The agreements with certain of the foregoing senior management contain post-termination non-competition covenants that generally may last for a period of 12 months post-termination and entitle the executives to their base salary, or portion thereof, during the period.

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

Warrant Incentive Program

Our employees, consultants, advisors and board members are eligible to participate in our warrant incentive program. Warrants have been issued by the general meeting or by our board of directors pursuant to valid authorizations in our articles of association and the terms and conditions have, in accordance with the Danish Companies Act, been incorporated in our articles of association as in effect from time to time. Each warrant grants the holder the right to subscribe for one ordinary share against cash payment of the exercise price. The exercise price is determined by our board of directors and historically has not been less than the estimated fair value of our ordinary shares on the date of grant. Our board of directors is authorized to issue an additional 1,237,525 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 519,049 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 68,436 outstanding warrants granted in connection with our preference D financing, there are four annual exercise periods that continue for 21 days following the day of publication of (i) our interim report (three-month report); (ii) the annual report notification—or if such notification is not published—the annual report; (iii) our interim report (six-month report); and (iv) our interim

report (nine-month report). For these warrants, the last exercise period is 21 days following the publication of our interim report (nine-month report) in 2023. For 5,232,726 outstanding warrants granted on or after December 18, 2015, there are four annual exercise periods; each exercise period begins two full trading days after the publication of the public release of our earnings data of a fiscal quarter and continues until the end of the second-to-last trading day in which quarter the relevant earnings release is published. The warrants granted on or after December 18, 2015 expire ten years after the grant date.

The table below sets forth information regarding outstanding warrants held by those members of our board of directors and senior management who assuming the exercise of warrants beneficially own 1% or more of our total outstanding ordinary shares as of March 1, 2020.

Name	Grant Date	Awards granted and outstanding	Awards granted and outstanding, but unvested as of March 1, 2020	Award Exercise Price(s)	Award Expiration Date
Jan Møller Mikkelsen	December 3, 2012	299,372	—	€ 7.9962	21 days following our interim report (six-month report) in 2023
	November 26, 2014	31,624	—	€ 6.4775	21 days following our interim report (nine-month report) in 2023
	December 18, 2015	217,000	—	€15.6750	December 18, 2025
	December 14, 2016	180,000	30,000	€19.4194	December 14, 2026
	December 12, 2017	200,000	83,334	€31.5995	December 12, 2027
	December 11, 2018	200,000	133,334	€54.6357	December 11, 2028
	December 10, 2019	120,000	110,000	€97.4993	December 10, 2029
James I. Healy, M.D., Ph.D.	December 18, 2015	35,000	—	€15.6750	December 18, 2025
	December 14, 2016	15,000	—	€19.4194	December 14, 2026
	December 12, 2017	15,000	—	€31.5995	December 12, 2027
	December 11, 2018	13,000	4,334	€54.6357	December 11, 2028
	December 10, 2019	7,500	6,250	€97.4993	December 10, 2029
Albert Cha, M.D., Ph.D.	December 18, 2015	35,000	—	€15.6750	December 18, 2025
	December 14, 2016	15,000	—	€19.4194	December 14, 2026
	December 12, 2017	15,000	—	€31.5995	December 12, 2027
	December 11, 2018	13,000	4,334	€54.6357	December 11, 2028
	December 10, 2019	7,500	6,250	€97.4993	December 10, 2029

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 II") who were elected at the annual general meeting held in 2018 for a term expiring at the annual general meeting to be held 2020; and a second class of directors ("Class I") who were elected at the annual general meeting held in 2019 for a term expiring at the annual general meeting to be held in 2021. The shareholders shall increase or decrease the number of directors, to ensure that the two classes shall be as nearly equal in number as possible; provided, however, that no decrease shall have the effect of shortening the term of any other director. At each annual general meeting beginning in 2016, the successors of the class of directors whose term expires at that meeting shall be elected to hold office for a term expiring at the annual general meeting held in the second year following the year of their election.

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

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

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

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

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

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

Executive Board

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

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

Director Independence

Our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise their ability to exercise independent judgment in carrying out the responsibilities of a director. As a result of this review, our board of directors determined that Lisa Bright, Albert Cha, M.D., Ph.D., James I. Healy, M.D., Ph.D., Birgitte Volck, M.D., Ph.D., and Lars Holtug, representing five of our seven directors, are "independent directors" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of Nasdaq. In making such determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining the director's independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities (if any).

Committees of the Board of Directors

We have an audit committee, a remuneration committee and a nominating and corporate governance committee. We have adopted a charter for each of these committees. Under Danish corporate law, it is not possible to delegate the decision making authority of the entire board of directors to board committees.

Audit Committee

Our audit committee consists of Lars Holtug (Chairman), Lisa Bright and James I. Healy, M.D., Ph.D. Each member satisfies the independence requirements of the Nasdaq listing standards, and Lars Holtug qualifies as an "audit committee financial expert," as defined in Item 16A of Form 20-F and as determined by our board of directors. Our audit committee oversees our accounting and financial reporting processes and the audits of our consolidated financial statements. As a foreign private issuer, we are not required to have a formal written audit committee charter that complies with Nasdaq Rule 5605(c)(1) and, although we have adopted an audit committee charter, we comply with home country practices in lieu of Nasdaq Rule 5605(c)(1). Nasdaq Rule 5605(c)(2)(A) requires that U.S. listed companies have an audit committee composed of at least three members, each of whom is an independent director, as defined in the Nasdaq rules. As a foreign private issuer, we are exempt from complying with the Nasdaq requirement to have an audit committee with at least three members, and we comply with home country practices in lieu of Nasdaq Rule 5605(c)(2)(A). However, our audit committee currently comprises three members, all of whom meet the relevant criteria for independence under Nasdaq rules and under Rule 10A-3 of the Exchange Act. Our audit committee is responsible for, among other things:

- making recommendations to our board of directors regarding the appointment by the general meeting of shareholders of our independent auditors;
- overseeing the work of the independent auditors, including making recommendations to the board of directors and resolving disagreements between the executive board and the independent auditors relating to financial reporting;
- reviewing the independence and quality control procedures of the independent auditors;
- discussing material off-balance sheet transactions, arrangements and obligations with the executive board and the independent auditors;
- reviewing all proposed related-party transactions;
- discussing the annual audited consolidated and statutory financial statements with the executive board;
- annually reviewing and reassessing the adequacy of our audit committee charter;
- meeting separately with the independent auditors to discuss critical accounting policies, recommendations on internal controls, the auditor's engagement letter and independence letter and other material written communications between the independent auditors and the executive board; and
- attending to such other matters as are specifically delegated to our audit committee by our board of directors from time to time.

Remuneration Committee

Our remuneration committee consists of Albert Cha, M.D., Ph.D. (Chairman), Lisa Bright and Lars Holtug. Each member satisfies the independence requirements of the Nasdaq listing standards. Our remuneration committee assists our board of directors in reviewing and approving or recommending our compensation structure, including all forms of compensation relating to our board of director and the executive board. As a foreign private issuer, we are not required to have a formal written remuneration committee charter that complies with Nasdaq Rule 5605(d)(1) and, although we have adopted a remuneration committee charter, we comply with home country practices in lieu of Nasdaq Rule 5605(d)(1). Our remuneration committee is responsible for, among other things:

- reviewing and making recommendations to our board of directors with respect to compensation of our executive board and members of our board of directors;
- reviewing and approving the compensation, including equity compensation, change-of-control benefits and severance arrangements, of our chief executive officer, chief financial officer and such other members of our executive board as it deems appropriate;

- overseeing and making recommendations to our board of directors regarding the evaluation of our executive board;
- reviewing periodically and making recommendations to our board of directors with respect to any incentive compensation and equity plans, programs or similar arrangements; and
- attending to such other matters as are specifically delegated to our compensation committee by our board of directors from time to time.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of James I. Healy, M.D., Ph.D. (Chairman), Albert Cha, M.D., Ph.D., and Birgitte Volck, M.D., Ph.D. Each member satisfies the independence requirements of the Nasdaq listing standards. Our nominating and corporate governance committee assists the board of directors in selecting individuals qualified to become our board members and in determining the composition of the board of directors and its committees. Our nominating and corporate governance committee is responsible for, among other things:

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

For information on current term of office and the period during which the members of our board of directors, executive board and our senior management have served in office see "Item 6A. Directors, Senior Management and Employees—Directors and Senior Management."

D. Employees

As of December 31, 2019, we employed 330 full-time employees, 121 of whom hold a Ph.D., M.D., or equivalent degrees. Of these full-time employees, 250 were engaged in research and development and 80 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 Program."

Item 7 Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth information relating to the beneficial ownership of our shares as of March 1, 2020, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding ordinary shares;
- each of our board members; and
- each member of our senior management, including members of our executive board.

The number of shares beneficially owned by each entity, person, member of our board of directors or senior management is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to subscribe for within 60 days of March 1, 2020 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 47,985,837 ordinary shares outstanding as of March 1, 2020. Ordinary shares that a person has the right to subscribe for within 60 days of March 1, 2019 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights but are not deemed outstanding for purposes of computing the percentage ownership of any other person. Additionally, a person is considered to have the right to subscribe for ordinary shares which are subject to outstanding warrants and vested within 60 days of March 1, 2020, although such warrants may only be exercised in prescribed exercise periods. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Ascendis Pharma A/S, at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark.

Name and Address of Beneficial Owner	Number of Outstanding Shares Beneficially Owned	Number of Warrants Exercisable Within 60 Days	Number of Shares Beneficially Owned	Percentage of Beneficial Ownership
T. Rowe Price Associates, Inc.(1)	7,761,296	—	7,761,296	16.2%
Entities affiliated with FMR LLC(2)	4,773,953	—	4,773,953	9.9%
Entities affiliated with RA Capital Management, LLC(3)	4,185,342	—	4,185,342	8.7%
Baker Bros. Advisors LP(4)	3,390,270	—	3,390,270	7.1%
Entities affiliated with OrbiMed Private Investments V, L.P.(5)	3,287,400	—	3,287,400	6.9%
Senior Management and Board Members				
Jan Møller Mikkelsen(6)	638,740	891,328	1,530,068	3.1%
Vibeke Miller Breinholt, Ph.D.(7)	—	9,292	9,292	*
Flemming Steen Jensen(8)	—	83,500	83,500	*
Michael Wolff Jensen, L.L.M.(9)	—	109,860	109,860	*
Thomas A. Larson(10)	—	38,250	38,250	*
Sigurd Okkels, Ph.D.(11)	—	24,750	24,750	*
Dana Pizzuti, M.D.(12)	—	5,833	5,833	*
Juha Punnonen, M.D., Ph.D.(13)	—	41,833	41,833	*
Scott T. Smith(14)	—	101,000	101,000	*
Kennett Sprogøe, Ph.D.(15)	30	111,000	111,030	*
Lotte Sønderbjerg(16)	—	131,308	131,308	*
Peter Rasmussen(17)	—	52,999	52,999	*
Lisa Bright(18)	—	49,707	49,707	*
Albert Cha, M.D., Ph.D.(19)	2,190,980	74,916	2,265,896	4.7%
James I. Healy, M.D., Ph.D.(20)	2,090,850	74,916	2,165,766	4.5%
Lars Holtug, M.Sc.(21)	—	13,645	13,645	*
Birgitte Volck, M.D., Ph.D.(22)	404	41,357	41,357	*

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

(1) Consists of 7,761,296 ordinary shares and ADSs held by T. Rowe Price Associates, Inc. (“Price Associates”) as reported on Schedule 13G filed on February 14, 2020 by Price Associates. Price Associates, may be deemed to have sole power to vote over 2,374,324 shares and sole power to dispose of 7,761,296 shares. The address of Price Associates is 100 E. Pratt Street, Baltimore, Maryland 21202.

(2) Consists of an aggregate of 4,773,953 ordinary shares and ADSs beneficially owned, or that may be deemed to be beneficially owned, by FMR LLC, certain of its affiliates and other companies as reported on Amendment No. 4 to Schedule 13G filed on February 7, 2020 by FMR LLC. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders’ voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders’ voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act (“Fidelity Funds”) advised by Fidelity Management & Research Company (“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 3,492,794 ADSs held by RA Capital Healthcare Fund, L.P. (the “RA Fund”) and 692,548 ADSs held in a separately managed account (the “RA Account”) as reported by Amendment No. 8 to Schedule 13G filed with the SEC on February 14, 2020. RA Capital Healthcare Fund GP, LLC is the general partner of the RA Fund. The general partner of RA Capital Management, L.P. (“RA Capital”) is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are the controlling persons. RA Capital serves as investment adviser for the RA Fund and the RA Account and may be deemed a beneficial owner of the shares held by the RA Fund and the RA Account. The RA Fund has delegated to RA Capital the sole power to vote and the sole power to dispose of all securities held in the RA Fund’s portfolio. The RA Fund, RA Capital, Mr. Kolchinsky and Mr. Shah disclaim beneficial ownership of the shares described herein. The address of the RA Fund, the RA Capital, Mr. Kolchinsky and Mr. Shah is c/o RA Capital Management, L.P., 200 Berkeley Street, 18th Floor, Boston, MA 02116.

(4) Consists of (i) 3,128,395 ordinary shares and ADSs held by Baker Brothers Life Sciences, L.P. and (ii) 261,875 ordinary shares and ADSs held by 667, L.P. (together with Baker Brothers Life Sciences, L.P., the “Funds”) as reported on Amendment No. 2 to Schedule 13G filed on February 14, 2020 by Baker Bros. Advisors LP (the “Adviser”), Baker Bros. Advisors (GP) LLC (the “Adviser GP”), Felix J. Baker and Julian C. Baker (collectively, “Baker Bros.”). Pursuant to the management agreements, as amended, among the Adviser, the Funds and their respective general partners, the Funds’ respective general partners relinquished to the Adviser all discretion and authority with respect to the investment and voting power of the securities held by the Funds, and thus the Adviser has complete and unlimited discretion and authority with respect to the Funds’ investments and voting power over investments. The Adviser GP, Felix J. Baker and Julian C. Baker as principals of the Adviser GP, and the Adviser may be deemed to be beneficial owners of securities directly held by the Funds and may be deemed to have the power to vote or direct the vote of and the power to dispose or direct the disposition of such securities. The address of Baker Bros. is c/o Baker Bros. Advisors LP, 860 Washington Street, 3rd Floor, New York, NY 10014.

(5) Consists of (i) 2,950,900 ADSs held by OrbiMed Private Investment V, LP ("OPI V"), (ii) 61,000 ADSs held by OrbiMed Global Healthcare Master Fund, L.P. ("OGH"), (iii) 154,000 ADSs held by OrbiMed Partners Master Fund Limited ("OrbiMed Master Fund"), and (iv) 121,500 ADSs held by The Worldwide Healthcare Trust Plc ("WWH") as reported by Amendment No. 12 to Schedule 13D filed with the SEC on August 14, 2019. OrbiMed Advisors LLC ("OrbiMed Advisors") is the sole managing member of GP V, which is the sole general partner of OPI V. OrbiMed Advisors is the investment advisor to OGH. OrbiMed Capital LLC ("OrbiMed Capital") acts as the investment advisor to OrbiMed Master Fund and is the portfolio manager to WWH. OrbiMed Advisors exercises investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of such shares held by OPI V and OGH. OrbiMed Capital exercises investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of such shares held by OrbiMed Master Fund and WWH. By virtue of such relationships, GP V, OrbiMed Advisors, Mr. Gordon, Mr. Borho and Mr. Silverstein may be deemed to have voting and investment power with respect to the shares held by OPI V and OGH and may be deemed to have beneficial ownership of such shares. By virtue of such relationships, OrbiMed Capital, Mr. Gordon, Mr. Borho and Mr. Silverstein may be deemed to have voting and investment power with respect to the shares held by OrbiMed Master Fund and WWH and may be deemed to have beneficial ownership of such shares. The address of OPI V, OGH, GP V, OrbiMed Advisors, OrbiMed Capital, OrbiMed Master Fund, WWH, Mr. Gordon, Mr. Borho and Mr. Silverstein is 601 Lexington Avenue, 54th Floor, New York, NY 10022.

(6) Consists of (i) 638,740 ordinary shares held by Mr. Mikkelsen and (ii) 891,328 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Mr. Mikkelsen. Does not reflect the transfer of shares to the spouse of Mr. Mikkelsen, which is expected to occur in connection with a separation which may be completed in 2020.

(7) Consists of 9,292 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Dr. Breinholt.

(8) Consists of 83,500 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Mr. Jensen.

(9) Consists of 109,860 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Mr. Jensen.

(10) Consists of 38,250 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Mr. Larson.

(11) Consists of 24,750 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Dr. Okkels.

(12) Consists of 5,833 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Dr. Pizzuti.

(13) Consists of 41,833 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Dr. Punnonen.

(14) Consists of 101,000 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Mr. Smith.

(15) Consists of (i) 111,000 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Dr. Sprogøe and (ii) 30 ADSs held by family members of Dr. Sprogøe.

(16) Consists of 131,308 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Ms. Sønderbjerg.

(17) Consists of 52,999 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Mr. Rasmussen.

(18) Consists of 49,707 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Ms. Bright.

(19) Consists of (i) 74,916 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Dr. Cha, (ii) an aggregate of 1,760,739 ordinary shares and ADSs held by Vivo Ventures Fund VII, L.P. ("Vivo VII LP"), (iii) an aggregate of 38,373 ordinary shares and ADSs held by Vivo Ventures VII Affiliates Fund, L.P. ("Vivo VII Affiliates LP"), and (iv) an aggregate of 391,868 ordinary shares and ADSs held by Vivo Opportunity Fund, L.P. ("Vivo Opportunity LP"). Vivo Ventures VII, LLC is the general partner of each of Vivo VII LP and Vivo VII Affiliates LP and may be deemed to have shared power to vote and shared power to dispose of the shares directly owned by Vivo VII LP and Vivo VII Affiliates LP. Vivo Opportunity, LLC is the general partner of Vivo Opportunity LP and may be deemed to have shared power to vote and shared power to dispose of the shares directly owned by Vivo Opportunity LP. The managing members of Vivo Ventures VII, LLC are Drs. Albert Cha, Edgar Engleman, Frank Kung, Chen Yu and Mr. Shan Fu and may be deemed to have shared voting and dispositive power over the shares directly owned by Vivo VII LP and Vivo VII Affiliates LP. The managing members of Vivo Opportunity, LLC are Drs. Albert Cha, Frank Kung, Gaurav Aggarwal and Mrs. Shan Fu and Michael Chang and may be deemed to have shared voting and dispositive power over the shares directly owned by Vivo Opportunity LP. The address for each of Vivo VII LP, Vivo VII Affiliates LP and Vivo Opportunity LP is c/o 192 Lytton Avenue, Palo Alto, CA 94301.

(20) Consists of (i) 74,916 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Dr. Healy, (ii) 2,080,800 ordinary shares and ADSs held by Sofinnova Venture Partners IX, L.P. ("SVP IX") and (iii) 10,050 ordinary shares and ADSs held by Sofinnova Management IX, L.L.C. ("SM IX"). SM IX is the general partner of SVP IX and may be deemed to have sole

power to vote and sole power to dispose of shares directly owned by SVP IX. Dr. James I. Healy, and Michael Powell, the managing members of SM IX, may be deemed to have shared voting and dispositive power over the shares directly owned by each of SVP IX and SM IX. Each of Dr. Healy and Mr. Powell disclaim beneficial ownership over the shares held by SVP IX and SM IX, except to the extent of their pecuniary interests therein. The address of SVP IX is c/o Sofinnova Ventures, Inc., 3000 Sand Hill Road, Bldg. 4, Suite 250, Menlo Park, California 94025.

(21) Consists of 13,645 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Dr. Holtug.

(22) Consists of (i) 41,357 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of March 1, 2020 by Dr. Volck and (ii) 404 ADSs held by family members of Dr. Volck.

Record holders

As of March 1, 2020, assuming that all of our ordinary shares represented by ADSs are held by residents of the United States, approximately 98.7% of our outstanding ordinary shares were held in the United States by four holders of record and 1.3% of our outstanding ordinary shares were held outside of the United Stated by one holder of record. At such date, there were outstanding 46,154,279 ADSs, each representing one of our ordinary shares, and in the aggregate representing 96.2% of our outstanding ordinary shares. At such date, there were five holders of record registered with the Bank of New York Mellon, depositary of the ADSs. The actual number of holders is greater than these numbers of record holders and includes beneficial owners whose ADSs are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

B. Related Party Transactions

The following is a description of related party transactions we have entered into since January 1, 2019 with any of our board members, our senior management, the owners of more than five percent of our share capital, and any other related parties.

Employment Agreements and Warrant Grants

We have entered into employment agreements with, and issued warrants to, the members of our senior management and our independent board of directors. In addition, we are paying fees for board tenure and board committee tenure to the independent members of our board of directors. See Item 6.B. “Directors, Senior Management and Employees—Compensation” for more information.

Indemnification Agreements

We have entered into indemnification agreements with our board members and members of our senior management. See Item 6.B. “Directors, Senior Management and Employees—Compensation—Insurance and Indemnification” for a description of these indemnification agreements.

Visen Pharmaceuticals

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

C. Interests of Experts and Counsel

Not applicable.

Item 8 Financial Information

A. Consolidated Statements and Other Financial Information

See the financial statements beginning on page F-1.

Legal Proceedings

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

Dividends

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

B. Significant Changes

See Note 21 to the audited consolidated financial statements included elsewhere in this annual report.

Item 9 The Offer and Listing

A. Offer and Listing Details

The ADS have been listed on The Nasdaq Global Select Market under the symbol "ASND" since January 28, 2015. Prior to that date, there was no public trading market for ADSs or our ordinary shares.

B. Plan of Distribution

Not applicable.

C. Markets

The ADS have been listed on The Nasdaq Global Select Market under the symbol "ASND" since January 28, 2015.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10 Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Authorizations to Our Board of Directors

As of the date of this Form 20-F, our board of directors is authorized to increase the share capital as follows:

- Our board of directors is authorized to increase our share capital by up to 9,000,000 shares without pre-emptive subscription rights for existing shareholders in connection with cash contributions, debt conversion and contributions in kind, provided, however, that the capital increases are carried out at market value. This authorization is valid until May 28, 2024.
- Our board of directors is authorized to increase our share capital by up to 9,000,000 shares with pre-emptive subscription rights for existing shareholders in connection with cash contributions, provided, however, that the capital increases are carried out at market value. This authorization is valid until May 28, 2024.
- Our board of directors is authorized to issue an additional 1,237,525 warrants and to increase our share capital by up to 1,237,525 shares without pre-emptive subscription rights for existing shareholders in connection with the exercise, if any, of said warrants and to determine the terms and conditions thereof. Our board of directors cannot issue warrants pursuant to this authorization to the extent that already issued and still outstanding warrants under this authorization amount to 20% or more of our share capital. This authorization is valid until May 28, 2023.
- Our board of directors is, without pre-emptive rights for the existing shareholders, authorized to obtain loans against issuance of convertible notes which confer the right to subscribe up to 9,000,000 shares. The convertible notes shall be offered at a subscription price and a conversion price that correspond in aggregate to at least the market price of the shares at the time of the decision of our board of directors to issue the convertible notes. The loans shall be paid in cash and our board of directors shall determine the terms and conditions for the convertible notes. This authorization is valid until May 28, 2024.
- Our board of directors is authorized at one or more times to increase the Company's share capital in favor of its employees and the employees of its subsidiaries with up to nominal DKK 500,000 without pre-emptive subscription rights for the Company's shareholders. This authorization is valid until May 23, 2021.

If our board of directors exercises its authorizations in full, and all warrants and convertible debt instruments are exercised fully (not including already issued warrants), then our share capital will amount to 76,723,362 shares consisting of 76,723,362 shares with a nominal value of DKK 1 each.

Owners' Register

We are obligated to maintain an owners' register (in Danish: *ejerbog*). The owners' register is maintained by Computershare A/S (Company Registration (CVR) no. 27088899), our Danish share registrar and transfer agent. It is mandatory that the owners' register is maintained within the European Union and that it is available to public authorities.

Pursuant to the Danish Companies Act, public and private limited liability companies are required to register with the Danish Business Authority information regarding shareholders who own at least 5% of the share capital or the voting rights. Pursuant to this provision, we file registrations with the Public Owners' Register of the Danish Business Authority. Shareholders that exceed the ownership threshold must notify us and we will subsequently file the information with the Danish Business Authority. Reporting is further required upon reaching thresholds of 10%, 15%, 20%, 25%, 33 1/3%, 50%, 66 2/3%, 90% and 100%.

Articles of Association and Danish Corporate Law

With respect to our articles of association, the following should be emphasized:

Objects Clause

Our corporate object, as set out in article 3 of our articles of association, is to develop ideas and preparations for the combating of disease medically, to manufacture and sell such preparations or ideas, to own shares of companies with the same objects and to perform activities in natural connection with these objects.

Summary of Provisions Regarding the Board of Directors and the Executive Board

Pursuant to our articles of association, our board of directors shall be elected by our shareholders at the general meeting and shall be composed of not less than three and no more than 10 members. With respect to the duration of the term which our board members severally hold office, the board of directors is classified into two classes as nearly equal in number as possible. Such classes consist of one class of directors ("Class II") who were elected at the annual general meeting held in 2018 for a term expiring at the annual general meeting to be held in 2020; and a second class of directors ("Class I") who were elected at the annual general meeting held in 2019 for a term expiring at the annual general meeting to be held in 2021. The shareholders shall increase or decrease the number of directors, in order to ensure that the two classes shall be as nearly equal in number as possible; provided, however, that no decrease shall have the effect of shortening the term of any other director. At each annual general meeting, the successors of the class of directors whose term expires at that meeting shall be elected to hold office for a term expiring at the annual general meeting held in the second year following the year of their election. Board members must retire from the board of directors at the annual general meeting following their 75th birthday. Board members are not required to own any shares of our share capital.

The board of directors shall appoint and employ an executive board consisting of one to five members to attend to our day-to-day management, and the board of directors shall determine the terms and conditions of the employment.

Voting Rights

Each shareholder is entitled to one vote for each share owned at the time of any general meeting. As compared with Danish citizens, there are no limitations under the articles of association or under Danish law on the rights of foreigners or non-Danish citizens to hold or vote our shares.

Dividend Rights

Our shareholders may at general meetings authorize the distribution of ordinary and extraordinary dividends. Our shareholders may not distribute dividends in excess of the recommendation from our board of directors and may only pay out dividends from our distributable reserves, which are defined as results from operations carried forward and reserves that are not bound by law after deduction of loss carried forward.

Our shareholders are eligible to receive any dividends declared and paid out. However, we have not to date declared or paid any dividends and we currently intend to retain all available financial resources and any earnings generated by our operations for use in the business and we do not anticipate paying any dividends in the foreseeable future. The payment of any dividends in the future will depend on a number of factors, including our future earnings, capital requirements, financial condition and future prospects, applicable restrictions on the payment of dividends under Danish law and other factors that our board of directors may consider relevant.

See "Item 10 E. Additional Information—Taxation" for a summary of certain tax consequences in respect of dividends or distributions to holders of our ordinary shares or the ADSs.

Pre-emptive Subscription Rights

Under Danish law, all shareholders have pre-emptive subscription rights in connection with capital increases that are carried out as cash contributions. An increase in share capital can be resolved by the shareholders at a general meeting or by the board of directors pursuant to an authorization given by the shareholders. In connection with an increase of a company's share capital, the shareholders may, by resolution at a general meeting, approve deviations from the general Danish pre-emptive rights of the shareholders. Under the Danish Companies Act, such resolution must be adopted by the affirmative vote of shareholders holding at least a two-thirds majority of the votes cast and the share capital represented at the general meeting.

The board of directors may resolve to increase our share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations set forth above under the caption "Authorizations to Our Board of Directors."

Unless future issuances of new shares and/or pre-emptive rights are registered under the Securities Act or with any authority outside Denmark, U.S. shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights.

Rights on Liquidation

Upon a liquidation or winding-up of our company, shareholders will be entitled to participate, in proportion to their respective shareholdings, in any surplus assets remaining after payment of our creditors.

Limitations on Holding of Shares

There are no limitations on the right to hold shares under the articles of association or Danish law.

Liability to Capital Calls by Us

Under our articles of association as well as the Danish Companies Act, our shareholders are not obligated to pay further amounts to us. All our shares are fully-paid.

Sinking Fund Provisions

There are no sinking fund provisions or similar obligations relating to our ordinary shares.

Disclosure Requirements

Pursuant to Section 55 of the Danish Companies Act, a shareholder is required to notify us when such shareholder's stake represents 5% or more of the voting rights in our company or the nominal value accounts for 5% or more of the share capital, and when a change of a holding already notified entails that the limits of 5%, 10%, 15%, 20%, 25%, 50%, 90% or 100% and the limits of one-third and two-thirds of the share capital's voting rights or nominal value are reached or are no longer reached. The notification shall be given within two weeks following the date when the limits are reached or are no longer reached.

The notification shall provide information about the full name, address or, in the case of undertakings, registered office, the number of shares and their nominal value and share classes as well as information about the basis on which the calculation of the holdings has been made. In the event that the shareholder is a non-resident company or citizen of Denmark, the notification shall include documentation, which clearly identifies the owner. The company shall cause the notification to be entered in the owners' register.

Upon the implementation of adopted legislation in Denmark, we will be obligated to collect and store for a period of at least five years certain information regarding the beneficial owners of shares in the Company. A beneficial owner is a physical person that directly or indirectly controls a shareholder. The Company shall cause such information to be registered with the Danish Business Authority.

The legal status of the notification obligations is not fully clarified in relation to ADS holders and an ADS holder may be subject to such obligations.

General Meetings

The general meeting of shareholders is the highest authority in all matters, subject to the limitations provided by Danish law and the articles of association. The annual general meeting shall be held in the Greater Copenhagen area not later than the end of May in each year.

At the annual general meeting, the audited annual report is submitted for approval, together with the proposed appropriations of profit/treatment of loss, the election of the board of directors and election of our auditors. In addition, the board of directors reports on our activities during the past year.

General meetings are convened by the board of directors with a minimum of two weeks' notice and a maximum of four weeks' notice by letter, fax or by e-mail. A convening notice will also be forwarded to shareholders recorded in our owners' register, who have requested such notification and by publication in the Danish Business Authority's computerized information system and on the company's website.

At the latest, two weeks before a general meeting (inclusive of the day of the general meeting), we shall make the following information and documents available on our webpage:

- the convening notice,
- the documents that shall be presented at the general meeting, and
- the agenda and the complete proposals.

Shareholders are entitled to attend general meetings, either in person or by proxy, and they or their proxy may be accompanied by one advisor. A shareholder's right to attend general meetings and to vote at general meetings is determined on the basis of the shares that the shareholder holds on the registration date. The registration date shall be one week before the general meeting is held. The shares which the individual shareholder holds are calculated on the registration date on the basis of the registration of ownership in the owners' register as well as notifications concerning ownership which the Company has received with a view to update the ownership in the owners' register. In addition, any shareholder who is entitled to attend a general meeting and who wishes to attend must have requested an admission card from us no later than three days in advance of the general meeting.

Any shareholder is entitled to submit proposals to be discussed at the general meetings. However, proposals by the shareholders to be considered at the annual general meeting must be submitted in writing to the board of directors not later than six weeks before the annual general meeting.

Extraordinary general meetings must be held upon resolution of an annual general meeting to hold such a meeting or upon request of the board of directors, our auditors or shareholders representing at least 1/20 of the registered share capital or such lower percentage as our articles of association may provide. Our articles of association do not state such lower percentage.

Holders of ADSs are not entitled to directly receive notices or other materials or to attend or vote at general meetings.

Resolutions in General Meetings

Resolutions made by the general meeting generally may be adopted by a simple majority of the votes cast, subject only to the mandatory provisions of the Danish Companies Act and our articles of association. Resolutions concerning all amendments to the articles of association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder's ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose or increase any obligations of the shareholders towards the company require unanimity.

Quorum Requirements

There are no quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares.

Squeeze Out

According to Section 70 of the Danish Companies Act, shares in a company may be redeemed in full or in part by a shareholder holding more than nine-tenths of the shares and the corresponding voting rights in the company. Furthermore, according to Section 73 of the Danish Companies Act, a minority shareholder may require a majority shareholder holding more than nine-tenths of the shares and the corresponding voting rights to redeem the minority shareholder's shares.

Danish Rules Intended to Prevent Market Abuse

As of July 3, 2016, EU Regulation No 596/2014 on market abuse entered into force and Chapter 10 of the Danish Securities Trading Act was repealed. Pursuant to said Chapter 10, we had adopted an internal code on inside information in respect of the holding of and carrying out of transactions by our board of directors and executive officers and employees in the shares or ADSs or in financial instruments the value of which is determined by the value of the ordinary shares or ADSs, and we had drawn up a list of those persons working for us who could have access to inside information on a regular or incidental basis and had informed such persons of the rules on insider trading and market manipulation, including the sanctions which could be imposed in the event of a violation of those rules. However, said EU Regulation No 596/2014 on market abuse imposes no such requirements on us and we have therefore taken steps to abandon our previous practice.

Limitation on Liability

Under Danish law, members of the board of directors or senior management may be held liable for damages in the event that loss is caused due to their negligence. They may be held jointly and severally liable for damages to the company and to third parties for acting in violation of the articles of association and Danish law.

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

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

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

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

Comparison of Danish Corporate Law and Our Articles of Association and Delaware Corporate Law

The following comparison between Danish corporate law, which applies to us, and Delaware corporate law, the law under which many publicly traded companies in the United States are incorporated, discusses additional matters not otherwise described in this prospectus. This summary is subject to Danish law, including the Danish Companies Act, and Delaware corporate law, including the Delaware General Corporation Law. Further, please note that ADS holders will not be treated as our shareholders and will not have any shareholder rights.

Duties of Board Members

Denmark. Public limited liability companies in Denmark are usually subject to a two-tier governance structure with the board of directors having the ultimate responsibility for the overall supervision and strategic management of the company in question and with an executive board/management being responsible for the day-to-day operations.

Each board member and member of the executive board/management is under a fiduciary duty to act in the interest of the company but shall also take into account the interests of the creditors and the shareholders. Under Danish law, the members of the board of directors and executive management of a limited liability company are liable for losses caused by negligence whether shareholders, creditors or the company itself suffers such losses. They may also be liable for wrongful information given in the annual financial statements or any other public announcements from the company. An investor suing for damages is required to prove its claim with regard to negligence and causation. Danish courts, when assessing negligence, have been reluctant to impose liability unless the directors and officers neglected clear and specific duties. This is also the case when it comes to liability with regard to public offerings or liability with regard to any other public information issued by the company.

Delaware. The board of directors bears the ultimate responsibility for managing the business and affairs of a corporation. In discharging this function, directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. Delaware courts have decided that the directors of a Delaware corporation are required to exercise informed business judgment in the performance of their duties. Informed business judgment means that the directors have informed themselves of all material information reasonably available to them. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

Terms of the Members of Our Board of Directors

Denmark. Under Danish law, the members of the board of directors of a limited liability company are generally appointed for an individual term of one year. There is no limit on the number of consecutive terms the board members may serve. Pursuant to our articles of association, our board members are appointed by the general meeting of shareholders for a term of two years and are divided into two classes. Election of board members is, according to our articles of association, an item that shall be included on the agenda for the annual general meeting.

At the general meeting, shareholders are entitled at all times to dismiss a board member by a simple majority vote.

It follows from Section 140 of the Danish Companies Act that in limited liability companies that have employed an average of at least 35 employees in the preceding three years, the employees are entitled to elect a minimum of two representatives and alternate members to the company's board of directors up to one half the number of the shareholder elected directors. If the number of representatives to be elected by the employees is not a whole number, such number must be rounded up.

Our company currently employs more than an average of 35 employees and has done so since 2016. Consequently, from 2018, our employees will be entitled to demand representation on our board of directors. The question will, upon request from the employees, be put to a popular vote among the employees. If more than half of the employees (regardless whether they participate in the vote) vote in favor of having representation, we must organize an election process.

Additionally, Section 141 of the Danish Companies Act allows for group representation on the board of directors of our Company, i.e. that employees of our Danish subsidiaries may demand representation on our board. However, our Danish subsidiaries do not currently have employees. The employees of Ascendis Pharma, Inc., and the employees of our other foreign subsidiary, Ascendis Pharma GmbH, may only demand representation on our board of directors provided that our general meeting adopts a resolution to that effect.

Delaware. The Delaware General Corporation Law generally provides for a one-year term for directors, but permits directorships to be divided into up to three classes, of relatively equal size, with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the stockholders. A director elected to serve a term on a "classified" board may not be removed by stockholders without cause. There is no limit in the number of terms a director may serve.

Board Member Vacancies

Denmark. Under Danish law, in the event of a vacancy, new board members are elected by the shareholders in a general meeting. Thus, a general meeting will have to be convened to fill a vacancy on the board of directors. However, the board of directors may choose to wait to fill vacancies until the next annual general meeting of the company, provided that the number of the remaining board members is more than two, and provided that the remaining board members can still constitute a quorum. It is only a statutory requirement to convene a general meeting to fill vacancies if the number of remaining members on the board is less than three.

Delaware. The Delaware General Corporation Law provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (1) otherwise provided in the certificate of incorporation or bylaws of the corporation or (2) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Conflict-of-Interest Transactions

Denmark. Under Danish law, board members may not take part in any matter or decision-making that involves a subject or transaction in relation to which the board member has a conflict of interest with us.

Delaware. The Delaware General Corporation Law generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- the material facts as to the director's relationship or interest are disclosed and a majority of disinterested directors' consent;
- the material facts are disclosed as to the director's relationship or interest and a majority of shares entitled to vote thereon consent; or
- the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the stockholders.

Proxy Voting by Board Members

Denmark. In the event that a board member in a Danish limited liability company is unable to participate in a board meeting, the elected alternate, if any, shall be given access to participate in the board meeting. Unless the board of directors has decided otherwise, or as otherwise is set out in the articles of association, the board member in question may grant a power of attorney to another board member, provided that this is considered safe considering the agenda in question.

Delaware. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Shareholder Rights

Notice of Meeting

Denmark. According to the Danish Companies Act, general meetings in limited liability companies shall be convened by the board of directors with a minimum of two weeks' notice and a maximum of four weeks' notice as set forth in the articles of association. A convening notice shall also be forwarded to shareholders recorded in our owners' register, who have requested such notification. There are specific requirements as to the information and documentation required to be disclosed in connection with the convening notice.

Delaware. Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.

Voting Rights

Denmark. Each ordinary share confers the right to cast one vote at the general meeting of shareholders, unless the articles of association provide otherwise. Each holder of ordinary shares may cast as many votes as it holds shares. Shares that are held by us or our direct or indirect subsidiaries do not confer the right to vote.

Delaware. Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event can a quorum consist of less than one third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than ten days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

Shareholder Proposals

Denmark. According to the Danish Companies Act, extraordinary general meetings of shareholders will be held whenever our board of directors or our appointed auditor requires. In addition, one or more shareholders representing at least 1/20th of the registered share capital of the company may, in writing, require that a general meeting be convened. If such a demand is forwarded, the board of directors shall convene the general meeting within two weeks thereafter.

All shareholders have the right to present proposals for adoption at the annual general meeting, provided that the proposals are forwarded at the latest six weeks prior thereto. In the event that the proposal is received at a later date, the board of directors will decide whether the proposal has been forwarded in due time to be included on the agenda.

Delaware. Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting of stockholders. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least $2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

Action by Written Consent

Denmark. Under Danish law, it is permissible for shareholders to take action and pass resolutions by written consent in the event of unanimity; however, this will normally not be the case in listed companies and for a listed company, this method of adopting resolutions is generally not feasible.

Delaware. Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

Appraisal Rights

Denmark. The concept of appraisal rights does not exist under Danish law, except in connection with statutory redemptions rights according to the Danish Companies Act.

According to Section 73 of the Danish Companies Act, a minority shareholder may require a majority shareholder that holds more than 90% of the company's registered share capital and votes to redeem his or her shares. Similarly, a majority shareholder holding more than 90% of the company's share capital and votes may, according to Section 70 of the same act, squeeze out the minority shareholders. In the event that the parties cannot agree to the redemption squeeze out price, this shall be determined by an independent evaluator appointed by the court. Additionally, there are specific regulations in Sections 249, 267, 285 and 305 of the Danish Companies Act that

require compensation in the event of national or cross-border mergers and demergers. Moreover, shareholders who vote against a cross-border merger or demerger are, according to Sections 286 and 306 of the Danish Companies Act, entitled to have their shares redeemed.

Delaware. The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

Shareholder Suits

Denmark. Under Danish law, only a company itself can bring a civil action against a third party; an individual shareholder does not have the right to bring an action on behalf of a company. An individual shareholder may, in its own name, have an individual right to take action against such third party in the event that the cause for the liability of that third party also constitutes a negligent act directly against such individual shareholder.

Delaware. Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

Repurchase of Shares

Denmark. Danish limited liability companies may not subscribe for newly issued shares in their own capital. Such company may, however, according to the Danish Companies Act Sections 196-201, acquire fully paid shares of its own capital provided that the board of directors has been authorized thereto by the shareholders acting in a general meeting. Such authorization can only be given for a maximum period of five years and the authorization shall fix (i) the maximum value of the shares and (ii) the minimum and the highest amount that the company may pay for the shares. Shares may generally only be acquired using distributable reserves.

Delaware. Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

Anti-takeover Provisions

Denmark. Under Danish law, it is possible to implement limited protective anti-takeover measures. Such provisions may include, among other things, (i) different share classes with different voting rights, (ii) specific requirements to register the shares named in the company's owners register and (iii) notification requirements concerning participation in general meetings. We have currently not adopted any such provisions.

Delaware. In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits "business combinations," including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation's voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transaction;
- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or
- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until 12 months following its adoption.

Inspection of Books and Records

Denmark. According to Section 150 of the Danish Companies Act, a shareholder may request an inspection of the company's books regarding specific issues concerning the management of the company or specific annual reports. If approved by shareholders with simple majority, one or more investigators are elected. If the proposal is not approved by simple majority but 25% of the share capital votes in favor, then the shareholder can request the court to appoint an investigator.

Delaware. Under the Delaware General Corporation Law, any stockholder may inspect certain of the corporation's books and records, for any proper purpose, during the corporation's usual hours of business.

Pre-emptive Rights

Denmark. Under Danish law, all shareholders have pre-emptive subscription rights in connection with capital increases that are carried out as cash contributions. In connection with an increase of a company's share capital, the shareholders may, by resolution at a general meeting, approve deviations from the general Danish pre-emptive rights of the shareholders. Under the Danish Companies Act, such resolution must be adopted by the affirmative vote of shareholders holding at least a two-thirds majority of the votes cast and the share capital represented at the general meeting.

The board of directors may resolve to increase our share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations described above under the caption "Authorizations to Our Board of Directors."

Unless future issuances of new shares are registered under the Securities Act or with any authority outside Denmark, U.S. shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights.

Delaware. Under the Delaware General Corporation Law, stockholders have no pre-emptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

Dividends

Denmark. Under Danish law, the distribution of ordinary and extraordinary dividends requires the approval of a company's shareholders at a company's general meeting. The shareholders may not distribute dividends in excess of the recommendation from the board of directors and may only pay out dividends from our distributable reserves, which are defined as results from operations carried forward and reserves that are not bound by law after deduction of loss carried forward. It is possible under Danish law to pay out interim dividends. The decision to pay out interim

dividends shall be accompanied by a balance sheet, and the board of directors determine whether it will be sufficient to use the balance sheet from the annual report or if an interim balance sheet for the period from the annual report period until the interim dividend payment shall be prepared. If interim dividends are paid out later than six months following the financial year for the latest annual report, an interim balance sheet showing that there are sufficient funds shall always be prepared.

Delaware. Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of shares, property or cash.

Shareholder Vote on Certain Reorganizations

Denmark. Under Danish law, all amendments to the articles of association shall be approved by the general meeting of shareholders with a minimum of two-thirds of the votes cast and two-thirds of the represented share capital. The same applies to solvent liquidations, mergers with the company as the discontinuing entity, mergers with the company as the continuing entity if shares are issued in connection therewith and demergers. Under Danish law, it is debatable whether the shareholders must approve a decision to sell all or virtually all of the company's business/assets.

Delaware. Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

However, under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, unless required by the certificate of incorporation, if (1) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (2) the shares of stock of the surviving corporation are not changed in the merger and (3) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

Amendments to Governing Documents

Denmark. All resolutions made by the general meeting may be adopted by a simple majority of the votes, subject only to the mandatory provisions of the Danish Companies Act and the articles of association. Resolutions concerning all amendments to the articles of association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder's ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose any or increase any obligations of the shareholders towards the company require unanimity.

Delaware. Under the Delaware General Corporation Law, a corporation's certificate of incorporation may be amended only if adopted and declared advisable by the board of directors and approved by a majority of the outstanding shares entitled to vote, and the bylaws may be amended with the approval of a majority of the outstanding shares entitled to vote and may, if so provided in the certificate of incorporation, also be amended by the board of directors.

C. Material Contracts

Except as otherwise disclosed in this annual report (including the Exhibits), we are not currently party to any material contract, other than contracts entered into in the ordinary course of business.

D. Exchange Controls

There are no laws or regulation in Denmark that restrict the export or import of capital (except for certain investments in certain domains in accordance with applicable resolutions by the United Nations or the European Union), including, but not limited to, foreign exchange controls, or which affect the remittance of dividends, interest or other payments to non-resident holders of our ordinary shares.

E. Taxation

Danish Tax Considerations

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

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

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

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

Taxation of Danish Tax Resident Holders of the ADSs

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

Sale of the ADSs (Individuals)

Gains from the sale of shares are taxed as share income at a rate of 27% on the first DKK 55,300 (for cohabiting spouses, a total of DKK 110,600) and at a rate of 42% on share income exceeding DKK 55,300 (for cohabiting spouses over DKK 110,600). Such amounts are subject to annual adjustments and include all share income (*i.e.*, all capital gains and dividends derived by the individual or cohabiting spouses, respectively).

Gains and losses on the sale of shares are calculated as the difference between the purchase price and the sales price. The purchase price is generally determined using the average method (in Danish "gennemsnitsmetoden") as a proportionate part of the aggregate purchase price for all the shareholder's shares in the company.

Losses on non-listed shares may be offset against other share income, (*i.e.*, received dividends and capital gains on the sale of shares). Unused losses will automatically be offset against a cohabiting spouse's share income. In case the share income becomes negative, a negative tax on the share income will be calculated and offset against the individual's other final taxes. Unused negative tax on share income will be offset against a cohabiting spouse's final taxes. If the negative tax on share income cannot be offset against a cohabiting spouse's final taxes, the negative tax can be carried forward indefinitely and offset against future year's taxes.

Sale of the ADSs (Companies)

For the purpose of taxation of sales of shares made by shareholders (Companies), a distinction is made between Subsidiary Shares, Group Shares, Tax-Exempt Portfolio Shares and Taxable Portfolio Shares (note that the ownership threshold described below is applied on the basis of the number of all shares issued by the company, and not on the basis of the number of the ADSs issued):

"*Subsidiary Shares*" is generally defined as shares owned by a shareholder holding at least 10% of the nominal share capital of the issuing company.

"*Group Shares*" is generally defined as shares in a company in which the shareholder of the company and the issuing company are subject to Danish joint taxation or fulfill the requirements for international joint taxation under Danish law (*i.e.*, the company is controlled by the shareholder).

"*Tax-Exempt Portfolio Shares*" is defined as shares not admitted to trading on a regulated market owned by a shareholder holding less than 10% of the nominal share capital of the issuing company.

"*Taxable Portfolio Shares*" is defined as shares that do not qualify as Subsidiary Shares, Group Shares or Tax-Exempt Portfolio Shares.

Gains or losses on disposal of Subsidiary Shares and Group Shares and Tax-Exempt Portfolio Shares are not included in the taxable income of the shareholder.

Special rules apply with respect to Subsidiary Shares and Group Shares to prevent exemption through certain holding company structures just as other anti-avoidance rules may apply. These rules will not be described in further detail.

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

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

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

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

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

Dividends (Individuals)

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

Dividends (Companies)

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

Dividends paid on Tax-Exempt Portfolio Shares are partly taxable as 70% of the dividends received are included in the taxable income, which is equivalent to an effective taxation of 15.4% (70% of 22%) irrespective of ownership period.

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

The actual withholding tax rate is as a starting point 27%, while it can be reduced (0%, 15.4%, 22%) if certain requirements are met. A claim for repayment can be made within 2 months or the excess tax will offset the corporation income tax for the year. The statute of limitation is 3 years.

Taxation of Shareholders Residing Outside Denmark

Sale of the ADSs (Individuals and Companies)

Holders of the ADSs not resident in Denmark are normally not subject to Danish taxation on any gains realized on the sale of shares, irrespective of the ownership period, subject to certain anti-avoidance rules seeking to prevent that taxable dividend payments are converted to tax exempt capital gains. If an investor holds the ADSs in connection with a trade or business conducted from a permanent establishment in Denmark, gains on shares may be included in the taxable income of such activities pursuant to the rules applying to Danish tax residents as described above.

Dividends (Individuals)

Under Danish law, dividends paid in respect of shares are generally subject to Danish withholding tax at a rate of 27%. Non-residents of Denmark are not subject to additional Danish income tax in respect to dividends received on shares.

If the withholding tax rate applied is higher than the applicable final tax rate for the shareholder, a request for a refund of Danish tax in excess hereof can be made by the shareholder in the following situations:

Reduction according to a tax treaty

In the event that the shareholder is a resident of a state with which Denmark has entered into a tax treaty, the shareholder may generally, through certain certification procedures, seek a refund from the Danish tax authorities of the tax withheld in excess of the applicable treaty rate, which is typically 15%. Denmark has entered into tax treaties with approximately 80 countries, including the United States, Switzerland and almost all members of the European Union. The tax treaty between Denmark and the United States generally provides for a 15% tax rate.

Reduction according to Danish tax law

If the shareholder holds less than 10% of the nominal share capital (in the form of ordinary shares in the company and not on the basis of the number of the ADSs issued) of the company and the shareholder is tax resident in a state which has a tax treaty or an international agreement, convention or other administrative agreement on assistance in tax matters according to which the competent authority in the state of the shareholder is obligated to exchange information with Denmark, dividends are subject to tax at a rate of 15%. If the shareholder is tax resident outside the European Union, it is an additional requirement for eligibility for the 15% tax rate that the shareholder together with related shareholders holds less than 10% of the nominal share capital of the company.

Note that the reduced tax rate does not affect the withholding rate, which is why the shareholder must claim a refund as described above in order to benefit from the reduced rate.

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

Dividends (Companies)

Dividends from Subsidiary Shares are tax exempt provided that the taxation of the dividends is to be waived or reduced in accordance with the Parent-Subsidiary Directive (2011/96/EEC) or in accordance with a tax treaty with the jurisdiction in which the company investor is resident. If Denmark is to reduce taxation of dividends to a foreign company under a tax treaty, Denmark will not—as a matter of domestic law—exercise such right and will in general not impose any tax at all. Further, dividends from Group Shares—not also being Subsidiary Shares—are exempt from Danish tax provided the company investor is a resident of the European Union or the EEA and provided the taxation of dividends should have been waived or reduced in accordance with the Parent-Subsidiary Directive (2011/96/EEC) or in accordance with a tax treaty with the country in which the company investor is resident had the shares been Subsidiary Shares.

Dividends paid on both Tax-Exempt and Taxable Portfolio Shares are generally subject to tax at a rate of 22% irrespective of ownership period. While the actual withholding tax rate is as a starting point 27%, it can be reduced if certain requirements are met. If the withholding tax rate applied is higher than the applicable final tax rate for the shareholder, a request for a refund of Danish tax in excess hereof can be made by the shareholder in the following situations:

Reduction according to a tax treaty

In the event that the shareholder is a resident of a state with which Denmark has entered into a tax treaty, the shareholder may generally, through certain certification procedures, seek a refund from the Danish tax authorities of the tax withheld in excess of the applicable treaty rate, which is typically 15%. Denmark has entered into tax treaties with approximately 80 countries, including the United States and almost all members of the European Union. The tax treaty between Denmark and the United States generally provides for a 15% rate.

Reduction according to Danish tax law

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

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

Share Transfer Tax and Stamp Duties

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

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

The following discussion describes the material U.S. federal income tax consequences to U.S. Holders (as defined below) under present law of an investment in the ADSs. The effects of any applicable state or local laws, or other U.S. federal tax laws such as estate and gift tax laws, the alternative minimum tax, or the Medicare contribution tax on net investment income, are not discussed. This summary applies only to investors who hold the ADSs as capital assets (generally, property held for investment) and who have the U.S. dollar as their functional currency. This

discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury regulations promulgated thereunder, judicial decisions, published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, and the income tax treaty between the United States and Denmark, or the Treaty, all as in effect as of the date of this annual report. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below.

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

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons whose functional currency is not the U.S. dollar;
- persons holding the ADSs as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities, commodities or currencies;
- partnerships, S corporations or other entities or arrangements treated as partnerships or pass-through entities for U.S. federal income tax purposes;
- tax-exempt organizations or governmental organizations;
- persons who acquired the ADSs pursuant to the exercise of any employee share option or otherwise as compensation;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the ADSs being taken into account in an "applicable financial statement" (as defined in the Code);
- persons that own or are deemed to own 10% or more of our equity by vote or value;
- persons that hold their ADSs through a permanent establishment or fixed base outside the United States; and
- persons deemed to sell the ADSs under the constructive sale provisions of the Code.

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

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

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

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

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

Taxation of Dividends and Other Distributions on the ADSs

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

If we are eligible for benefits under the Treaty, dividends a U.S. Holder receives from us generally will be "qualified dividend income." If certain holding period and other requirements, including a requirement that we are not a PFIC in the year of the dividend or the immediately preceding year, are met, qualified dividend income of an individual or other non-corporate U.S. Holder generally will be subject to preferential tax rates. You should consult your tax advisor regarding the availability of these preferential tax rates under your particular circumstances.

As discussed in "Taxation—Danish Tax Considerations," payments of dividends by us may be subject to Danish withholding tax. The rate of withholding tax applicable to U.S. Holders that are eligible for benefits under the Treaty is reduced to a maximum of 15%. For U.S. federal income tax purposes, U.S. Holders will be treated as having received the amount of Danish taxes withheld by us, and as then having paid over the withheld taxes to the Danish taxing authorities. As a result of this rule, the amount of dividend income included in gross income for U.S. federal income tax purposes by a U.S. Holder with respect to a payment of dividends may be greater than the amount of cash actually received (or receivable) by the U.S. Holder from us with respect to the payment.

Dividends will generally constitute foreign source income for foreign tax credit limitation purposes. Subject to the discussion of the PFIC rules below, any tax withheld with respect to distributions on the ADSs at the rate applicable to a U.S. Holder may, subject to a number of complex limitations, be claimed as a foreign tax credit against such U.S. Holder's U.S. federal income tax liability or may be claimed as a deduction for U.S. federal income tax purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to the ADSs generally will constitute "passive category income." The rules with respect to the foreign tax credit are complex and involve the application of rules that depend upon a U.S. Holder's particular circumstances. You are urged to consult your tax advisor regarding the availability of the foreign tax credit under your particular circumstances.

Taxation of Disposition of the ADSs

Subject to the PFIC rules discussed below, you will recognize gain or loss on any sale, exchange or other taxable disposition of an ADS equal to the difference between the amount realized (in U.S. dollars) on the disposition of the ADS and your tax basis (in U.S. dollars) in the ADS. Any such gain or loss will be capital gain or loss, and will be long-term capital gain or loss if you have held the ADS for more than one year at the time of sale, exchange or other taxable disposition. Otherwise, such gain or loss will be short-term capital gain or loss. Long-term capital gains recognized by certain non-corporate U.S. Holders, including individuals, generally will be taxable at a reduced rate. The deductibility of capital losses is subject to limitations. Any such gain or loss you recognize generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes. You should consult your tax advisor regarding the proper treatment of gain or loss in your particular circumstances.

Passive Foreign Investment Company

Based on the market price of the ADSs and the value and composition of our income and assets, we do not believe we were a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2019. 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, regardless of whether we continue to meet the income or asset tests described above, unless we cease to be a PFIC and you make a “deemed sale” election with respect to the ADSs you hold. If such election is made, you will be deemed to have sold the ADSs you hold at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be subject to the consequences described below. After the deemed sale election, the ADSs with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

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

- the “excess distribution” or gain will be allocated ratably over your holding period for the ADSs,
- the amount allocated to the current taxable year, and any taxable year before the first taxable year in your holding period in which we were a PFIC, will be treated as ordinary income, and

- the amount allocated to each other year will be subject to the highest income tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

Gains (but not losses) realized on the sale of the ADSs cannot be treated as capital, even if you hold the ADSs as capital assets.

If we are treated as a PFIC with respect to you for any taxable year, to the extent any of our subsidiaries are also PFICs, you will be deemed to own your proportionate share of any such lower-tier PFIC, and you may be subject to the rules described in the preceding two paragraphs with respect to the shares of such lower-tier PFICs you would be deemed to own. As a result, you may incur liability for any "excess distribution" described above if we receive a distribution from such lower-tier PFICs or if any shares in such lower-tier PFICs are disposed of (or deemed disposed of). You should consult your tax advisor regarding the application of the PFIC rules to any of our subsidiaries.

Alternatively, a U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a "mark-to-market" election for such stock to elect out of the general tax treatment for PFICs discussed above. If you make a "mark-to-market" election for the ADSs, you will include in income for each year we are a PFIC an amount equal to the excess, if any, of the fair market value of the ADSs as of the close of your taxable year over your adjusted basis in such ADSs. You are allowed a deduction for the excess, if any, of the adjusted basis of the ADSs over their fair market value as of the close of the taxable year. However, deductions are allowable only to the extent of any net "mark-to-market" gains on the ADSs included in your income for prior taxable years. Amounts included in your income under a "mark-to-market" election, as well as gain on the actual sale or other disposition of the ADSs, are treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any "mark-to-market" loss on the ADSs, as well as to any loss realized on the actual sale or disposition of the ADSs to the extent the amount of such loss does not exceed the net "mark-to-market" gains previously included for the ADSs. Your basis in the ADSs will be adjusted to reflect any such income or loss amounts. If you make a valid "mark-to-market" election, the tax rules that apply to distributions by corporations that are not PFICs would apply to distributions by us, except the lower applicable tax rate for qualified dividend income would not apply. If we cease to be a PFIC when you have a "mark-to-market" election in effect, gain or loss realized by you on the sale of the ADSs will be a capital gain or loss and taxed in the manner described above under "Taxation of Disposition of the ADSs."

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

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

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's

entire U.S. federal income tax return will remain open during such period. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules, taking into account the uncertainty as to whether we are currently treated as or may become a PFIC.

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

Information Reporting and Backup Withholding

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

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

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

Additional Reporting Requirements

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

F. Dividends and Paying Agents

Not applicable.

G. Statements by Experts

Not applicable.

H. Documents on Display

We are subject to the periodic reporting and other informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under the Exchange Act, we are required to file reports and other information with the SEC. Specifically, we are required to file annually a Form 20-F no later than four months after the close of each fiscal year, which is December 31. The SEC maintains a web site at www.sec.gov that contains reports, proxy and information statements, and other information regarding registrants that make electronic filings with the SEC using its EDGAR system. As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the furnishing and content of quarterly reports and proxy statements, and officers, directors and major shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

I. Subsidiary Information

Not applicable.

Item 11 Quantitative and Qualitative Disclosures About Market Risk

See “Item 5 Operating and Financial Review and Prospects—Quantitative and Qualitative Disclosures about Market Risk.”

Item 12 Description of Securities Other than Equity Securities

A. Debt Securities.

Not applicable.

B. Warrants and Rights.

Not applicable.

C. Other Securities.

Not applicable.

D. American Depositary Shares.

The Bank of New York Mellon, as depositary, registers and delivers American Depositary Shares, also referred to as ADSs. Each ADS represents one ordinary share (or a right to receive one ordinary share) deposited with The Bank of New York Mellon, London Branch, or any successor, as custodian for the depositary. Each ADS also represents any other securities, cash or other property which may be held by the depositary in respect of the depositary facility. The depositary’s corporate trust office at which the ADSs are administered and its principal executive office is located at 240 Greenwich Street, New York, New York 10286.

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

Fees and Expenses

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

Persons depositing or withdrawing ordinary shares or ADSs must pay:	***For:***
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	• Issue of ADSs, including issues resulting from a distribution of ordinary shares or rights or other property • Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$0.05 (or less) per ADS	• Any cash distribution to you
A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the shares had been deposited for issue of ADSs	• Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to you
$0.05 (or less) per ADS per calendar year	• Depositary services
Registration or transfer fees	• Transfer and registration of ordinary shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares

Expenses of the depositary	• Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement) • Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian have to pay on any ADS or share underlying an ADS, for example, share transfer taxes, stamp duty or withholding taxes	• As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	• As necessary

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

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

PART II

Item 13 Defaults, Dividend Arrearages and Delinquencies

Not applicable.

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

A. Material Modifications to the Rights of Securities Holders

Not applicable.

B. Use of Proceeds

Not applicable.

Item 15 Control and Procedures

A. Disclosure Controls and Procedures

Our chief executive officer and principal financial and accounting officers, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of December 31, 2019, have concluded that based on the evaluation of these controls and procedures required by Rule 13a-15(b) of the Exchange Act, our disclosure controls and procedures were effective.

B. Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting.

Internal control over financial reporting is defined in rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and

includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the audited consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect material misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. This assessment was performed under the directions and supervision of our Chief Executive Officer and our principal financial and accounting officers and based on the criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission.

A material weakness is a control deficiency, or a combination of control deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected. These control deficiencies could result in a misstatement of the financial statement accounts or related disclosures that would result in a material misstatement in the annual or interim consolidated financial statements that would not be prevented or detected on a timely basis. Based on management's assessment of those criteria, management has concluded that the design and operating effectiveness of our internal control over financial reporting was effective as of December 31, 2019.

The effectiveness of the Company's internal control over financial reporting has been audited by Deloitte Statsautoriseret Revisionspartnerselskab, our independent registered public accounting firm, as stated in their report on the Company's internal control over financial reporting as of December 31, 2019, which is included under Item 15C, below.

C. Attestation Report of the Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by Deloitte Statsautoriseret Revisionspartnerselskab, an independent registered public accounting firm, as stated in their report, which appears in Item 18 on page F-4.

D. Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the period covered by this annual report that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting.

Item 16A Audit Committee Financial Expert

Mr. Lars Holtug, an independent director and a member of the Audit Committee, qualifies as an "audit committee financial expert," as defined in Item 16A of Form 20-F and as determined by our board of directors.

Item 16B Code of Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, members of our senior management and members of our board of directors, including those members of our senior management responsible for financial reporting. Our code of ethics is posted on our company website at: http://www.ascendispharma.com. We will disclose any substantive amendments to the code of business conduct and ethics, or any waiver of its provisions, on our website. The reference to our website does not constitute incorporation by reference of the information contained at or available through our website.

Item 16C Principal Accountant Fees and Services

The following table sets forth, for each of the years indicated, the fees billed by our independent public accountants and the percentage of each of the fees out of the total amount billed by the accountants.

	Year ended December 31, 2019		Year ended December 31, 2018	
	EUR'000	%	EUR'000	%
Audit Fees	700	99%	693	92%
Audit-related Fees	—	—	—	—
Tax Fees	7	1%	—	—
All Other Fees	—	—	62	8%
Total	**707**	**100%**	**755**	**100%**

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

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

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

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

Pre-Approval Policies and Procedures for Non-Audit Services

Our Audit Committee has adopted a policy pursuant to which we will not engage our auditors to perform any non-audit services unless the audit committee pre-approves the service.

Item 16D Exemptions from the Listing Standards for Audit Committees

Not applicable.

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

None.

Item 16F Change in Registrants Certifying Accountant

None.

Item 16G Corporate Governance

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

- We do not intend to follow Nasdaq's quorum requirements applicable to meetings of shareholders. In accordance with Danish corporate law and generally accepted business practice, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders.

- We do not intend to follow Nasdaq's requirements regarding the provision of proxy statements for general meetings of shareholders. Danish corporate law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in Denmark. We do intend to provide shareholders with an agenda and other relevant documents for the general meeting of shareholders.
- We do not intend to follow Nasdaq's requirements regarding shareholder approval for certain issuances of securities under Nasdaq Rule 5635. Pursuant to Danish corporate law our shareholders have authorized our board of directors to issue securities including in connection with certain events such as the acquisition of shares or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us, rights issues at or below market price, certain private placements and issuance of convertible notes. We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act of 2002, the rules adopted by the SEC and Nasdaq's listing standards. As a Danish company not listed on a regulated market within the EU/EEA, we do not need to comply with the Danish corporate governance principles nor do we need to explain any deviation from these provisions in our Danish statutory annual report.
- We do not intend to follow Nasdaq's requirements regarding shareholder approval for all equity compensation plans. Generally, Nasdaq Rule 5635(c) requires each issuer to obtain shareholder approval of all equity compensation plans (including warrant incentive plans) and material amendments to such plans. However, pursuant to Nasdaq Rule 5615(a)(3), we have elected to follow our home country's practices (in this case, being Danish practices) in lieu of the requirements of Nasdaq Rule 5635(c). Our home country practices do not require us to obtain a shareholders' approval for amendments to our existing warrant incentive program.

Because we are a foreign private issuer, our members of our board of directors, executive board members and senior management are not subject to short-swing profit and insider trading reporting obligations under section 16 of the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act. They will, however, be subject to the obligations to report changes in share ownership under section 13 of the Exchange Act and related SEC rules.

Item 16H Mine Safety Disclosure

Not applicable.

PART III

Item 17 Financial Statements

See "Item 18 Financial Statements."

Item 18 Financial Statements

ASCENDIS PHARMA A/S

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Deloitte.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Ascendis Pharma A/S

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Ascendis Pharma A/S and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of profit or loss and other comprehensive income, the consolidated statements of changes in equity, and the consolidated cash flow statements for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated April 2, 2020, expressed an unqualified opinion on the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for leases from January 1, 2019 due to adoption of International Financial Reporting Standard 16 Leases.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Prepayment and Trade Payables - Clinical Trial Accruals — Refer to Notes 2 and 3 to the financial statements

Critical Audit Matter Description

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

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

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

How the Critical Audit Matter Was Addressed in the Audit

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

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

Deloitte Statsautoriseret Revisionspartnerselskab
CVR no. 33963556

/s/ Sumit Sudan
State Authorised Public Accountant

/s/ Lars Hansen
State Authorised Public Accountant

Copenhagen, Denmark

April 2, 2020

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

Deloitte.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Ascendis Pharma A/S

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Ascendis Pharma A/S and subsidiaries (the "Company") as of December 31, 2019, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2019, of the Company and our report dated April 2, 2020, expressed an unqualified opinion on those financial statements and included an explanatory paragraph regarding the Company's change in its method of accounting for leases from January 1, 2019 due to the adoption of International Financial Reporting Standard 16 Leases.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Deloitte Statsautoriseret Revisionspartnerselskab
CVR no. 33963556

/s/ Sumit Sudan
State Authorised Public Accountant

/s/ Lars Hansen
State Authorised Public Accountant

Copenhagen, Denmark

April 2, 2020

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

	Notes	2019	2018	2017
			(EUR'000)	
Revenue	**4**	13,375	10,581	1,530
Research and development costs		(191,621)	(140,281)	(99,589)
General and administrative expenses		(48,473)	(25,057)	(13,482)
Operating profit/(loss)		**(226,719)**	**(154,757)**	**(111,541)**
Share of profit/(loss) of associate	**11**	(8,113)	(321)	—
Finance income	**7**	17,803	24,714	923
Finance expenses	**7**	(1,221)	(127)	(13,756)
Profit/(loss) before tax		**(218,250)**	**(130,491)**	**(124,374)**
Tax on profit/(loss) for the year	**8**	234	394	477
Net profit/(loss) for the year		**(218,016)**	**(130,097)**	**(123,897)**
Other comprehensive income/(loss)				
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translating foreign operations		(37)	17	65
Other comprehensive income/(loss) for the year, net of tax		**(37)**	**17**	**65**
Total comprehensive income/(loss) for the year, net of tax		**(218,053)**	**(130,080)**	**(123,832)**
Profit/(loss) for the year attributable to owners of the Company		(218,016)	(130,097)	(123,897)
Total comprehensive income/(loss) for the year attributable to owners of the Company		(218,053)	(130,080)	(123,832)
		EUR	EUR	EUR
Basic and diluted earnings/(loss) per share		(4.69)	(3.17)	(3.68)
Number of shares used for calculation (basic and diluted) (1)		46,506,862	41,085,237	33,626,305

(1) A total of 5,820,211 warrants outstanding as of December 31, 2019 (a total of 5,611,629 warrants and 4,621,154 warrants outstanding as of December 31, 2018 and 2017, respectively) can potentially dilute earnings per share in the future but have not been included in the calculation of diluted earnings per share because they are antidilutive for the periods presented.

Consolidated Statements of Financial Position as of December 31,

	Notes	2019	2018
		(EUR'000)	
Assets			
Non-current assets			
Intangible assets	**9**	3,495	3,495
Property, plant and equipment	**10**	45,069	4,325
Investment in associate	**11**	15,538	17,083
Deposits	**17**	1,463	1,158
		65,565	**26,061**
Current assets			
Receivable from associate	**11, 17**	804	—
Trade receivables	**17**	—	6
Other receivables		3,136	1,775
Prepayments		7,648	12,415
Income taxes receivable		1,473	849
Cash and cash equivalents	**17**	598,106	277,862
		611,167	**292,907**
Total assets		**676,732**	**318,968**
Equity and liabilities			
Equity			
Share capital	**12**	6,443	5,659
Distributable equity	**13**	590,671	274,391
Total equity		**597,114**	**280,050**
Non-current liabilities			
Lease liabilities	**14**	30,720	—
Other payables		908	—
		31,628	**—**
Current liabilities			
Lease liabilities	**14**	5,899	—
Contract liabilities	**15**	858	6,902
Trade payables	**17**	27,765	19,740
Other payables		13,349	12,267
Income taxes payable		119	9
		47,990	**38,918**
Total liabilities		**79,618**	**38,918**
Total equity and liabilities		**676,732**	**318,968**

Consolidated Statements of Changes in Equity

	Distributable Equity (EUR '000)				
	Share Capital	Share Premium	Foreign Currency Translation Reserve	Share-based Payment Reserve	Accumulated Deficit	Total
Equity at January 1, 2017	**4,354**	**298,567**	**(79)**	**13,084**	**(139,313)**	**176,613**
Loss for the year	—	—	—	—	(123,897)	(123,897)
Other comprehensive loss, net of tax	—	—	65	—	—	65
Total comprehensive income/(loss)	**—**	—	**65**	**—**	**(123,897)**	**(123,832)**
Share-based payment (Note 6)	—	—	—	9,709	—	9,709
Capital increase	613	132,496	—	—	—	133,109
Cost of capital increase	—	(8,388)	—	—	—	(8,388)
Equity at December 31, 2017	**4,967**	**422,675**	**(14)**	**22,793**	**(263,210)**	**187,211**
Loss for the year	—	—	—	—	(130,097)	**(130,097)**
Other comprehensive loss, net of tax	—	—	17	—	—	**17**
Total comprehensive income/(loss)	**—**	—	**17**	**—**	**(130,097)**	**(130,080)**
Share-based payment (Note 6)	—	—	—	19,652	—	**19,652**
Capital increase	692	215,693	—	—	—	**216,385**
Cost of capital increase	—	(13,118)	—	—	—	**(13,118)**
Equity at December 31, 2018	**5,659**	**625,250**	**3**	**42,445**	**(393,307)**	**280,050**
Loss for the year	—	—	—	—	(218,016)	**(218,016)**
Other comprehensive loss, net of tax	—	—	(37)	—	—	**(37)**
Total comprehensive income/(loss)	**—**	—	**(37)**	**—**	**(218,016)**	**(218,053)**
Share-based payment (Note 6)	—	—	—	37,486	—	**37,486**
Capital increase	784	528,548	—	—	—	**529,332**
Cost of capital increase	—	(31,701)	—	—	—	**(31,701)**
Equity at December 31, 2019	**6,443**	**1,122,097**	**(34)**	**79,931**	**(611,323)**	**597,114**

Consolidated Cash Flow Statements for the year Ended December 31

	2019	2018	2017
		(EUR'000)	
Operating activities			
Net profit/(loss) for the year	**(218,016)**	**(130,097)**	**(123,897)**
Reversal of non-cash consideration regarding revenue	(6,522)	(10,508)	—
Reversal of share of profit/(loss) of associate	8,113	321	—
Reversal of finance income	(17,803)	(24,714)	(923)
Reversal of finance expenses	1,221	127	13,756
Reversal of tax charge	(234)	(394)	(477)
Adjustments for:			
Share-based payment	37,486	19,652	9,709
Depreciation and amortization	6,689	880	734
Changes in working capital:			
Deposits	(305)	(865)	(25)
Receivables	(1,877)	(183)	(671)
Prepayments	4,766	(5,508)	(4,945)
Trade payables and other payables	7,530	8,262	10,755
Contract liabilities (deferred income)	(6,044)	—	(94)
Cash flows generated from/(used in) operations	**(184,996)**	**(143,027)**	**(96,078)**
Finance income received	10,056	4,020	923
Finance expenses paid	(717)	(127)	(97)
Income taxes received/(paid)	(279)	332	153
Cash flows from/(used in) operating activities	**(175,936)**	**(138,802)**	**(95,099)**
Investing activities			
Acquisition of property, plant and equipment	(5,159)	(2,648)	(941)
Cash flows from/(used in) investing activities	**(5,159)**	**(2,648)**	**(941)**
Financing activities			
Finance lease liabilities	(4,038)	—	—
Capital increase	529,332	216,385	133,109
Cost of capital increase	(31,701)	(13,118)	(8,388)
Cash flows from/(used in) financing activities	**493,593**	**203,267**	**124,721**
Increase/(decrease) in cash and cash equivalents	**312,498**	**61,817**	**28,681**
Cash and cash equivalents at January 1	277,862	195,351	180,329
Effect of exchange rate changes on balances held in foreign currencies	7,746	20,694	(13,659)
Cash and cash equivalents at December 31	**598,106**	**277,862**	**195,351**
Restricted cash included in cash and cash equivalents	**5,776**	**5,566**	**63**

Note 1—General Information

Ascendis Pharma A/S, together with its subsidiaries, is a biopharmaceutical company applying its innovative TransCon technologies to build a leading, fully integrated biopharmaceutical company. Ascendis Pharma A/S was incorporated in 2006 and is headquartered in Hellerup, Denmark. Unless the context otherwise requires, references to the "Company," "we," "us," and "our", refer to Ascendis Pharma A/S and its subsidiaries.

The address of the Company's registered office is Tuborg Boulevard 12, DK-2900 Hellerup, Denmark. The Company's registration number in Denmark is 29918791.

On February 2, 2015, the Company completed an initial public offering, or IPO, which resulted in the listing of American Depositary Shares, or ADSs, representing the Company's ordinary shares, under the symbol "ASND" in the United States on The Nasdaq Global Select Market.

The Company's Board of Directors approved these consolidated financial statements on April 1, 2020.

Note 2—Summary of Significant Accounting Policies

Basis of Preparation

The consolidated financial statements are prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, and as adopted by the European Union, or EU.

The accounting policies applied when preparing the consolidated financial statements are described in detail below and are applied for all entities. Unless otherwise stated under the section "Changes in Accounting Policies and Disclosures" below, these policies have been applied consistently to all years presented. Significant accounting judgements and estimates used when exercising the accounting policies are described in Note 3.

Our consolidated financial statements have been prepared under the historical cost convention, apart from certain financial instruments that are measured at fair value at initial recognition.

Changes in Accounting Policies and Disclosures

Adoption of IFRS 16 "Leases"

As of January 1, 2019, the Company has adopted IFRS 16, "Leases" ("IFRS 16"). IFRS 16 requires, with a few exceptions, lessees to recognize assets ("right-of-use assets") and liabilities for most leases. Accordingly, lease payments under most contracts previously classified as operating leases, will be recognized over the non-cancellable lease period as depreciation included in research and development costs and general and administrative expenses, and as interest expenses included in finance expenses. Previously, lease payments under all operating leases were recognized as either research and development costs or general and administrative expenses.

We have implemented IFRS 16 by applying the modified retrospective approach. Accordingly, no comparative information is restated. The lease liability and corresponding right-of-use assets is measured at the present value of the remaining lease payments, discounted using an estimated incremental borrowing rate at January 1, 2019.

In connection with the transition to IFRS 16, we have reviewed our operating lease agreements' contractual terms including the lease payment structure. Fixed payments, and variable lease payments that depend on an index or a rate, are included in lease payments, whereas variable lease payments and payments related to non-lease components are excluded.

For lease arrangements other than those relating to short-term leases and leases of low value assets, lease liabilities have been determined according to the fixed lease payments and variable lease payments that depend on an index or a rate in the non-cancellable periods, discounted by the incremental borrowing rate. Accordingly, at January 1, 2019, we have recognized a lease liability of €17.7 million. For short-term leases and leases of low value assets, lease payments are recognized on a straight-line basis over the lease term in the consolidated statement of profit or loss as research and development costs or as general and administrative expenses, as appropriate.

Operating lease commitments under IAS 17 “Leases”, and as disclosed for the annual reporting period ended December 31, 2018 was €19.6 million. The transition to the lease liabilities recognized in the consolidated financial position at January 1, 2019, in accordance with IFRS 16, is summarized below:

	(EUR ‘000)
Operating lease commitments as per December 31, 2018	19,627
Short-term contracts and low value assets	(169)
Undiscounted, operating lease commitments as per January 1, 2019	19,458
Lease liabilities discounted by incremental borrowing rates as per January 1, 2019	**17,700**

At January 1, 2019, right-of-use assets of €18.4 million, which include prepaid leases, were recognized as property, plant and equipment.

The transition to IFRS 16 at January 1, 2019 had no impact on accumulated deficits.

Other New and Amended Standards and Interpretations

Several other amendments to and interpretations of IFRS apply for the first time in 2019, but do not have an impact on the accounting policies applied by the Company. Thus, except for the adoption of IFRS 16, the accounting policies applied when preparing these consolidated financial statements have been applied consistently to all the periods presented, unless otherwise stated.

Going Concern

The Company’s Board of Directors has, at the time of approving the consolidated financial statements, a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Thus, we continue to adopt the going concern basis of accounting in preparing the financial statements.

Recognition and Measurement

Assets are recognized in the consolidated statements of financial position when it is probable, as a result of a prior event, that future economic benefits will flow to us and the value of the asset can be measured reliably.

Liabilities are recognized in the consolidated statements of financial position when we have a legal or constructive obligation as a result of a prior event, and it is probable that future economic benefits will flow from us and the value of the liability can be measured reliably.

On initial recognition, assets and liabilities are measured at cost or at fair value, depending on the classification of the items. Measurement subsequent to initial recognition is affected as described below for each financial statement item. Events that arise before the time of presentation of the consolidated financial statements and that confirm or invalidate affairs and conditions existing at the consolidated financial statements date are considered. Financial statement items affected by those events are adjusted if those events provide evidence of conditions that existed at the consolidated financial statements date.

Income is recognized in the consolidated statements of profit or loss when earned, whereas costs are recognized by the amounts attributable to the financial year.

Basis of Consolidation

The consolidated financial statements include our parent company, Ascendis Pharma A/S, and all enterprises over which the parent company has control. We control an enterprise when we are exposed to, or have rights to, variable returns from our involvement with the enterprise and have the ability to control those returns through our power over the entity. Accordingly, the consolidated financial statements include Ascendis Pharma A/S and the subsidiaries listed in Note 19.

Consolidation Principles

The consolidated financial statements comprise the parent company and its subsidiaries at December 31, 2019. Subsidiaries, which are enterprises where we have control at the reporting date, are fully consolidated from the date upon which control is transferred to us. They are deconsolidated from the date control ceases.

We reassess whether the parent company controls an enterprise if facts and circumstances indicate that there are changes to one or more of the three elements of control, respectively:

- The contractual arrangement(s) with the other vote holders of the enterprise;
- The Company's voting rights and potential voting rights; and
- Rights arising from other contractual arrangements.

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

Subsidiaries and our associate apply accounting policies in line with the Company's accounting policies. When necessary, adjustments are made to bring the entities' accounting policies in line with those of the Company.

Investment in Associates

An associate is an entity over which we have significant influence over financial and operational decisions but where we have neither control nor joint control. The Company's associate is accounted for using the equity method. Under the equity method, the associate is initially recognized at cost. Thereafter, the carrying amount of the investment is adjusted to recognize changes in the Company's share of net assets of the associate since the acquisition or establishment date.

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

After application of the equity method, we determine whether it is necessary to recognize an impairment loss related to the associate. Accordingly, at each reporting date, we determine whether there is objective evidence that the associate is impaired. If there is such evidence, we calculate the amount of impairment as the difference between the recoverable amount of the associate and its carrying value. Any impairment loss is recognized within share of profit/(loss) of associate in the consolidated statements of profit or loss.

Foreign Currency

Functional and Presentation Currency

Items included in the consolidated financial statements are measured using the functional currency of each Group entity. Functional currency is the currency of the primary economic environment in which the entity operates. The consolidated financial statements are presented in Euro (EUR), which is also the functional currency of the parent company.

Translation of Transactions and Balances

On initial recognition, transactions in currencies other than the individual entity's functional currency are translated applying the exchange rate in effect at the date of the transaction. Receivables, payables and other monetary items denominated in foreign currencies that have not been settled at the reporting date are translated using the exchange rate in effect at the reporting date.

Exchange rate differences that arise between the rate at the transaction date and the rate in effect at the payment date, or the rate at the reporting date, are recognized in profit or loss as finance income or finance expenses. Property, plant and equipment, intangible assets and other non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions.

Currency Translation of Group Enterprises

When subsidiaries or associates that present their financial statements in a functional currency other than EUR are recognized in the consolidated financial statements, their statements of profit or loss are translated at average exchange rates. Balance sheet items are translated using the exchange rates at the reporting date. Exchange rate differences arising from translation of foreign entities' balance sheet items at the beginning of the year to the reporting date exchange rates as well as from translation of statements of profit or loss from average rates to the exchange rates at the reporting date are recognized in other comprehensive income. Similarly, exchange rate differences arising from changes that have been made directly in a foreign subsidiary's equity are recognized in other comprehensive income.

Business Combinations

Newly acquired or newly established subsidiaries are recognized in the consolidated financial statements from the time of acquiring or establishing such enterprises. Time of acquisition is the date on which we obtain control over the enterprise.

When acquiring new enterprises over which we obtain control, the acquisition method is applied. Under this method, we identify assets, liabilities and contingent liabilities of these enterprises and measure them at fair value at the acquisition date. Restructuring costs are only recognized in the pre-acquisition balance sheet if they constitute a liability of the acquired enterprise. Allowance is made for the tax effect of the adjustments made.

The acquisition price for an enterprise consists of the fair value of the consideration paid for the acquired enterprise. Costs that are attributable to the acquisition of the enterprise are recognized in the consolidated statement of profit or loss when incurred.

The excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the identifiable net assets acquired are all recorded as goodwill.

Goodwill is subject to an annual impairment test. Impairment is calculated as the difference between the recoverable amount of the cash-generating unit that the goodwill relates to, and its carrying amount. Any impairment loss is recognized in the consolidated statement of profit or loss in a separate line item.

Revenue

Our revenue is primarily generated from collaboration and license agreements. Further, we also generate revenue from development services under development and commercialization agreements, including delivery of clinical supply material. Additionally, revenue is generated from feasibility studies for potential partners to evaluate if our TransCon technologies enable certain advantages for their product candidates of interest. Such feasibility studies are often structured as short-term agreements with fixed fees for the work that we perform.

When we enter into contracts with customers, we assess the goods and/or services promised in the contract and identify distinct performance obligations. A promise in the agreement is considered a distinct performance obligation if both of the following criteria are met:

- the customer can benefit from the goods or services either on its own or together with other resources that are readily available to the customer (i.e., the goods or services is capable of being distinct); and
- the entity's promise to transfer the goods or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the goods or service is distinct within the context of the contract).

Under collaboration, license, and other agreements that contain multiple promises to the customer, the promises are identified and accounted for as separate performance obligations if these are distinct. If promises are not distinct, we combine those goods or services with other promised goods or services until we identify a bundle of goods or services that is distinct.

The transaction price in the contract is measured at fair value and reflects the consideration we expect to be entitled to in exchange for those goods or services. In the transaction price, variable consideration, including milestone payments, is only included to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The transaction price is allocated to each performance obligation according to their stand-alone selling prices and is recognized when control of the goods or services are transferred to the customer, either over time or at a point in time, depending on the specific terms and conditions in the contracts.

Revenue is stated net of value added tax and duties collected on behalf of a third party, and discounts. Usually, the payment terms are within one to two months. We have no payment terms exceeding 12 months, and thus transaction prices are not adjusted for financing components.

Research and Development Costs

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

Research costs comprise costs incurred at the early stages of the drug development cycle from the initial drug discovery and are recognized in the consolidated statement of profit or loss when incurred.

Research activities that evolve into a development project, typically involves a single product candidate undergoing a series of studies to illustrate its safety profile and effect on human beings prior to obtaining the necessary approval from the appropriate authorities. 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 when incurred.

Development costs also comprise manufacturing costs related to validation batches, or process performance qualification batches, on late-stage development projects. In addition, manufacturing costs related to pre-launch inventories are recognized as development costs, up until a biologics license application, or BLA, for the relevant drug candidate has been submitted and accepted by the authorities for further review.

General and Administrative Expenses

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

General and administrative expenses are recognized in the consolidated statement of profit or loss in the period to which they relate.

Share-based Incentive Programs

Share-based incentive programs under which board members, employees and select 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.

Where the terms and conditions for an equity-settled grant is modified, we recognize as minimum the services measured at the grant date fair value over the vesting period. Additionally, we re-measure the unvested grants at the date of modification and recognize any increase in the total fair value over the vesting period.

If a new grant is substituted for the cancelled grant and designated as a replacement grant on the date that it is granted, the cancelled and new grants are treated as if they were a modification of the original grant, as described in the previous paragraph.

Any social security contributions payable in connection with the grant or exercise of the warrants are recognized as expenses when incurred.

The assumptions used for estimating the fair value of share-based payment transactions are disclosed in Note 6.

Finance Income and Expenses

Finance income and expenses comprise interest income and expenses and realized and unrealized exchange rate gains and losses on transactions denominated in foreign currencies.

Interest income and interest expenses are stated on an accrual basis using the principal and the effective interest rate. The effective interest rate is the discount rate that is used to discount expected future cash payments or receipts through the expected life of the financial asset or financial liability to the amortized cost (the carrying amount), of such asset or liability.

Income Taxes

Tax for the year, which consists of current tax for the year and changes in deferred tax, is recognized in the consolidated statement of profit or loss by the portion attributable to the profit or loss for the year, and recognized directly in equity or other comprehensive income by the portion attributable to entries directly in equity and in other comprehensive income. The current tax payable or receivable is recognized in the 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 reporting date are used. Current tax payable is based on taxable profit or loss for the year. Taxable profit or loss differs from net profit or loss as reported in the consolidated statements of profit or loss because it excludes items of income or expense that are taxable or deductible in prior or future years. In addition, taxable profit or loss excludes items that are never taxable or deductible.

Deferred tax is recognized according to the balance sheet liability method of all temporary differences between carrying amounts and tax-based values of assets and liabilities, apart from deferred tax on all temporary differences occurring on initial recognition of goodwill or on initial recognition of a transaction which is not a business combination, and for which the temporary difference found at the time of initial recognition neither affects profit or loss nor taxable income.

Deferred tax liabilities are recognized on all temporary differences related to investments in our subsidiaries and/or associate, 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 reporting date are expected to apply when the deferred tax is expected to crystallize as current tax. Changes in deferred tax resulting from changed tax rates or tax rules are recognized in the consolidated statement of profit or loss unless the deferred tax is attributable to transactions previously recognized directly in equity or other comprehensive income. In the latter case, such changes are also recognized in equity or other comprehensive income.

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. Deferred tax assets are only offset against deferred tax liabilities if the entity, having recognized deferred tax assets has a legally enforceable right to set off current tax assets against current liabilities, and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same tax jurisdiction.

At every reporting date, it is assessed whether sufficient taxable income is likely to arise in the future for the deferred tax asset to be utilized.

Intangible Assets

Goodwill

Goodwill acquired in a business combination is initially measured at cost, being the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests over the net identifiable assets acquired and liabilities assumed.

After initial recognition, goodwill is measured at cost less any accumulated impairment losses. Goodwill is not amortized but is subject to impairment testing at least on a yearly basis. For the purpose of impairment testing, goodwill acquired in a business combination is allocated to each of the cash-generating units, or group of cash-generating units, that are expected to benefit from the synergies of the combination. Each cash-generating unit or group of cash-generating units to which goodwill is allocated represent the lowest level within the Company at which the goodwill is monitored for internal management purposes.

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 used in operation. Property, plant and equipment also comprise right-of-use assets. Please refer to the section “Leases”.

Subsequent costs are included in the carrying amount of the asset or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the assets will flow to us and the costs of the items can be measured reliably. All repair and maintenance costs are charged to the consolidated statement of profit or loss during the financial periods in which they are incurred.

Plant and equipment acquired for research and development activities with alternative use, which are expected to be used for more than one year, are capitalized and depreciated over the estimated useful life as research and development costs, as appropriate. Plant and equipment acquired for research and development activities, which have no alternative use, are recognized as research and development costs when incurred.

If the acquisition or use of the asset involves an obligation to incur costs of decommissioning or restoration of the asset, the estimated related costs are recognized as a provision and as part of the relevant asset's cost, respectively.

The basis for depreciation is cost less estimated residual value. The residual value is the estimated amount that would be earned if selling the asset today net of selling costs, assuming that the asset is of an age and a condition that is expected after the end of its useful life.

Cost of a combined asset is divided into smaller components, with such significant components depreciated individually if their useful lives vary.

Depreciation commences when the asset is available for use, which is when it is in the location and condition necessary for it to be capable of operating in the manner intended.

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

Process plant and machinery	5 - 10 years
Other fixtures and fittings, tools and equipment	3 - 5 years
Leasehold improvements	3 - 10 years
Right-of-use assets	2 - 10 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 and impairment losses of property, plant and equipment are recognized in the consolidated statement of profit or loss as research and development costs or as general and administrative expenses, as appropriate.

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

Impairment

The recoverable amount of goodwill is estimated annually irrespective of any recorded indications of impairment. Property, plant and equipment and finite-lived intangible assets are reviewed for impairment whenever events or circumstances indicate that the carrying amount may not be recoverable.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purpose of assessing impairment, assets are grouped at the lowest levels for which there are largely independent cash inflows, or cash-generating units, which for goodwill represent the lowest level within the enterprise at which the goodwill is monitored for internal management purposes. Prior impairments of non-financial assets, other than goodwill, are reviewed for possible reversal at each reporting date.

Receivables

Receivables comprise deposits, receivables from associate, trade receivables, and other receivables, which are separately presented in the consolidated statements of financial position.

Receivables (excluding receivables related to VAT and other indirect tax receivables) are classified as financial assets at amortized cost, as these are held to collect contractual cash flows and thus give rise to cash flows representing solely payments of principal and interest. Trade receivables are initially recognized at their transaction price and subsequently measured at amortized cost. Deposits are initially measured at their fair value and subsequently measured at amortized cost.

Other receivables comprise VAT and other indirect tax receivables, and thus not classified as financial assets, are measured at cost less impairment.

The carrying amounts of receivables usually equals their nominal value less provision for impairments.

Prepayments

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

Cash and Cash Equivalents

Cash and cash equivalents comprise cash and on-demand deposits with financial institutions. Cash and cash equivalents are measured at amortized cost.

Allowance for Expected Credit Losses on Financial Assets

Financial assets comprise receivables (excluding receivables relating to VAT and other indirect tax receivables) and cash and cash equivalents. Provision for bad debts is determined on the basis of a forward-looking expected credit loss ("ECL") model. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and the cash flows expected to be received, discounted by an approximation of the original effective interest rate.

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

For cash and cash equivalents, ECLs are assessed for credit losses that result from default events that are possible within the next 12-months ("12-month ECL"). In addition, since cash and cash equivalents are on-demand deposits, 12-month ECL are the same as lifetime ECL. However, being subject to assessing lifetime ECL following the general approach, credit risk is continuously tracked and monitored in order to identify significant deterioration. For those credit exposures for which there has been a significant increase in credit risk since initial recognition, an allowance is recognized for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default.

Shareholders' Equity

The share capital comprises the nominal amount of the parent company's ordinary shares, each at a nominal value of DKK 1, or approximately €0.13. All shares are fully paid.

Share premium reserve comprises the amounts received, attributable to shareholders' equity, in excess of the nominal amount of the shares issued at the parent company's capital increases, reduced by any expenses directly attributable to the capital increases.

Foreign currency translation reserve includes exchange rate adjustments relating to the translation of the results and net assets of our foreign operations from their functional currencies to our presentation currency. The accumulated reserve of a foreign operation is recognized in the consolidated statement of profit or loss at the time we lose control, and thus cease to consolidate such foreign operation. The foreign currency translation reserve is an unrestricted reserve that is available to be distributed as dividends to the Company's shareholders.

Reserve for share-based payment represents the corresponding entries to the share-based payment recognized in the consolidated statement of profit or loss, arising from our warrant programs.

Retained earnings or accumulated deficit represents the accumulated profits or losses from the Company's operations. A positive reserve is available to be distributed as dividends to the Company's shareholders.

Leases

With reference to “Changes to Accounting Policies and Disclosures”, the Company has adopted IFRS 16 “Leases” (“IFRS 16”), effective from January 1, 2019. Thus, until December 31, 2018, leases of property, plant and equipment, where we have substantially all of the risks and rewards of ownership, were classified as finance leases. Other leases were classified as operating leases. While no finance leases were in place at December 31, 2018 or December 31, 2017, all leases were classified as operating leases, and accordingly, all lease payments were recognized on a straight-line basis in the consolidated statement of profit or loss over the lease term.

From January 1, 2019, upon adoption of IFRS 16, we assess at contract inception whether a contract is, or contains, a lease, i.e., if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Except for short-term leases and leases of low value assets, we apply a single recognition and measurement approach as described below. For short-term leases and leases of low value assets, lease payments are recognized on a straight-line basis over the lease term in the consolidated statement of profit or loss as research and development costs or as general and administrative expenses, as appropriate.

The Company does not act as a lessor, neither does it act as a sub-lessor.

Right-of-use Assets

Right-of-use assets are recognized at the lease commencement date, defined as the date the underlying asset is available for use.

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

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

Lease Liabilities

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

When interest rates implicit in the lease contracts are not readily available, the present value of lease payments are calculated by applying the relevant lease holding entities’ incremental borrowing rates. Following the commencement date, the incremental borrowing rate is not changed unless the lease term is modified, or if the lease payments are modified and this modification results from a change in floating interest rates.

From the lease commencement date and over the lease term, the carrying amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in lease term, or a change in lease payments, including changes to future payments resulting from a change in an index used to determine such lease payments.

Trade Payables

Trade payables including accrued expenses are measured at amortized cost.

Other Payables

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

Contract Liabilities

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

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

Cash Flow Statement

The cash flow statement shows cash flows from operating, investing and financing activities as well as cash and cash equivalents at the beginning and the end of the financial year.

Cash flows from operating activities are presented using the indirect method and calculated as the profit or loss adjusted for non-cash items, working capital changes as well as finance income, finance expenses and income taxes paid.

Cash flows from investing activities 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 payments related to lease liabilities, and changes in the share capital of Ascendis Pharma A/S and related costs.

The effect of exchange rate changes on cash and cash equivalents held or due in a foreign currency is presented separately from cash flows from operating, investing and financing activities.

Cash flows in currencies other than the functional currency are recognized in the cash flow statement, using the average exchange rates.

Cash and cash equivalents comprise cash at hand and deposits with financial institutions.

Any restricted cash included in the balance of cash and cash equivalents is presented as an additional disclosure in the cash flow statement.

Segment Reporting

We are managed and operated as one operating and reportable segment. No separate operating segments or reportable segments have been identified in relation to product candidates or geographical markets. Accordingly, except for entity wide disclosures, we do not disclose segment information on business segments or geographical markets.

Basic EPS

Basic Earnings per Share, or EPS, is calculated as the consolidated net income or loss from continuing operations for the period divided by the weighted average number of ordinary shares outstanding.

Diluted EPS

Diluted earnings per share is calculated as the consolidated net income or loss from continuing operations for the period divided by the weighted average number of ordinary shares outstanding adjusted for the dilutive effect of share equivalents. If the consolidated statement of profit or loss shows a net loss, no adjustment is made for the dilutive effect, as such effect would be anti-dilutive.

New International Financial Reporting Standards Not Yet Effective

The IASB has issued, and the European Union has adopted, a number of new or amended standards, which have not yet become effective. Therefore, these new standards have not been incorporated in these consolidated financial statements. Our financial reporting is not expected to be affected by such new or improved standards.

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, please see below, made in the process of applying our accounting policies and that have the most significant effect on the amounts recognized in our consolidated financial statements.

Revenue Recognition

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

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

Critical judgments relating to specific revenue transactions are described below.

License Agreements

Judgments that significantly affect the determination of the amount and timing of revenue from contracts with customers relates to three license agreements, which were entered into in 2018.

Identifying Performance Obligations and Allocating Transaction Price

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

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

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

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

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

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

Share-Based Payment

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

We use the Black-Scholes option-pricing model to value the warrants granted and critical judgments need to be exercised in determining the appropriate input to the valuation model as well as to determine the appropriate way of recognizing the expenses under IFRS 2.

Warrants granted under our warrant programs vest on a monthly basis over periods of up to 48 months. Due to the graded vesting, the related expenses are recognized on an accelerated basis; i.e., each tranche of a warrant grant is treated separately for expense recognition purposes. Accordingly, the expenses related to each warrant grant is treated in up to 48 tranches, all being recognized over the vesting period.

See Note 6 for additional details on our warrant programs and recognition of expenses under IFRS 2.

Internally Generated Intangible Assets

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

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

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

Joint Arrangements / Collaboration Agreements

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

Key Sources of Estimation Uncertainty

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

Revenue Recognition—Allocation of Transaction Price to Performance Obligations

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

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

Impairment of Goodwill

Determining whether goodwill is impaired requires an estimation of the recoverable amount, being the higher of fair value less costs of disposal or value in use, of the cash-generating units to which goodwill has been allocated. The Company is determined to be a single cash-generating unit. Accordingly, the recoverable amount is determined based on an estimation of the Company's fair value less costs of disposal. We have determined the fair value of goodwill after taking into account the market value of our ADSs representing the enterprise value of the group enterprise as of the reporting date. No impairment loss has been recognized in 2019, 2018 or 2017. The carrying amount of goodwill at December 31, 2019 and 2018 was €3.5 million. See Note 9 for further details.

Recognition of Accruals and Prepayments for Development, 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 include estimation uncertainties as future efforts to complete the specific activity may be difficult to predict. We have reviewed all significant ongoing activities at the reporting date to determine the stage of completion compared to the invoices received and recognized accruals for any additional costs or prepayments for any invoiced costs in excess of the stage of completion. As of December 31, 2019, the consolidated statement of financial position included prepaid project costs of €5.8 million and accrued project costs of €10.5 million, compared to €11.4 million and €9.1 million, respectively, as of December 31, 2018.

Useful Lives of Property, Plant and Equipment

We review the estimated useful lives of property, plant and equipment at the end of each reporting period. We have concluded that the useful lives applied for 2019, 2018 and 2017 are appropriate.

Leases

In connection with adopting IFRS 16, the following are assessed as key assumptions concerning estimation uncertainty that have a significant risk of causing a material adjustment to the carrying amount of right-to-use assets and/or lease liabilities within the next financial year.

Lease Term

Certain lease arrangements provide us with a contractual right (not obligation) to either extend the lease after the initial term, or to terminate the lease within the enforceable lease term, i.e., periods where lessor cannot terminate the lease. Those options cover periods in the range from 1-6 years in addition to the non-cancellable periods. Based on our assessment at December 31, 2019, the lease terms reflect only the non-cancellable periods.

Incremental Borrowing Rate

Lease payments are discounted over the non-cancellable periods, applying each contract's incremental borrowing rate. In determining incremental borrowing rates, we have considered the contracts' specific payment profiles and relevant currencies, and applied a corresponding risk-free interest rate, credit spread, and an asset specific adjustment, if applicable. The incremental borrowing rates applied are 2.25-2.5% and 4.25-5.0% for lease contracts denominated in EUR or Danish Kroner, and U.S. Dollars, respectively.

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

Note 4—Revenue

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

	2019	2018	2017
		(EUR'000)	
Revenue from external customers			
Revenue from rendering of services (recognized over time)	9,919	1,215	1,530
Sale of clinical supply (recognized at a point in time)	804	—	—
"Right-to-use" licenses (recognized at a point in time)	2,652	9,366	—
Total revenue	**13,375**	**10,581**	**1,530**

	2019	2018	2017
		(EUR'000)	
Total revenue specified per geographical location			
North America	2,652	10,581	1,530
China	10,723	—	—
Total revenue	**13,375**	**10,581**	**1,530**

Revenue from a single customer was €13.4 million, €10.5 million, and €1.5 million for the financial years ended December 31, 2019, 2018 and 2017, respectively.

Note 5—Segment Information

The Company is managed and operated as one business unit. No separate business areas or separate business units have been identified in relation to product candidates or geographical markets. Accordingly, except for entity wide disclosures, we do not disclose information on business segments or geographical markets. Entity wide disclosures regarding revenue are included in Note 4.

The Company's intangible assets, and property, plant and equipment ("non-current segment assets") located by country are specified below (for 2019, the amounts include right-of-use assets, please also refer to Note 10):

	2019	2018
	(EUR'000)	
Non-current segment assets		
Denmark (domicile country)	15,738	4,922
North America	27,275	341
Germany	5,551	2,557
Total non-current segment assets	**48,564**	**7,820**
Investment in associate	15,538	17,083
Deposits	1,463	1,158
Total non-current assets	**65,565**	**26,061**

Note 6—Staff Cost

	2019	2018	2017
		(EUR'000)	
Wages and salaries	49,142	29,418	19,918
Share-based payment	37,486	19,652	9,709
Pensions (defined contribution plans)	648	444	324
Social security costs	3,613	1,793	1,156
Total staff costs	**90,889**	**51,307**	**31,107**
Average number of employees	**274**	**167**	**121**

Staff costs are recognized in the consolidated statement of profit or loss as follows:

	2019	2018	2017
		(EUR'000)	
Research and development costs	61,890	34,146	21,845
General and administrative expenses	28,999	17,161	9,262
Total staff costs	**90,889**	**51,307**	**31,107**

Key Management Personnel includes our Board of Directors and Executive Board and comprises 7 and 2 persons, respectively, for 2019 and 2018, and 8 and 2 persons, respectively, for 2017.

Compensation to Key Management Personnel comprises salaries, participation in annual bonus schemes, and share-based compensation. Share-based compensation is elaborated in further details in the section “Share-based Payment”.

Compensation to Key Management Personnel included within total staff costs are summarized below:

	2019	2018	2017
		(EUR’000)	
Wages and salaries	2,080	1,809	1,731
Share-based payment	7,167	5,112	3,576
Social security costs	94	152	70
Total Compensation to Key Management Personnel	**9,341**	**7,073**	**5,377**

Out of the total compensation to key management personnel, €2,129 thousand (2018: €1,851 thousand, 2017: €1,467 thousand) related to the Board of Directors, and €7,212 thousand (2018: €5,222 thousand, 2017: €3,910 thousand) related to the Executive Board. Out of the share-based payment to key management personnel, under the warrant programs described below, €1,864 thousand (2018: €1,607 thousand, 2017: €1,202 thousand) related to the Board of Directors, and €5,303 thousand (2018: €3,505 thousand, 2017: €2,374 thousand) related to the Executive Board.

Share-based payment

Ascendis Pharma A/S has established warrant programs, equity-settled share-based payment transactions, as an incentive for all of our employees, members of our Board of Directors and select external consultants.

Warrants are granted by the Board of Directors in accordance with authorizations given to it by the shareholders of Ascendis Pharma A/S. As of December 31, 2019, 9,378,787 warrants had been granted, of which 19,580 warrants have been cancelled, 3,271,250 warrants have been exercised, 2,168 warrants have expired without being exercised, and 265,578 warrants have been forfeited. As of December 31, 2019, our Board of Directors was authorized to grant up to 1,237,525 additional warrants to our employees, board members and select consultants without preemptive subscription rights for the shareholders of Ascendis Pharma A/S. Each warrant carries the right to subscribe for one ordinary share of a nominal value of DKK 1. The exercise price is fixed at the fair market value of our ordinary shares at the time of grant as determined by our board of directors. Vested warrants may be exercised in two or four annual exercise periods as described below. Apart from exercise prices and exercise periods, the programs are similar.

Vesting Conditions

Warrants issued during the period from 2008 to 2012 generally vested over 36 months with 1/36 of the warrants vesting per month from the date of grant. However, some of these warrants were subject to shorter vesting periods, to a minimum of 24 months. All such warrants have been exercised or have expired as of December 31, 2018.

Effective from December 2012, warrants granted generally vest over 48 months with 1/48 of the warrants vesting per month from the date of grant.

Effective from January 2015, certain warrants issued to board members vest over 24 months with 1/24 of the warrants vesting per month from the date of grant.

Warrants generally cease to vest from the date of termination in the event that (i) the warrantholder terminates the employment contract and the termination is not a result of breach of the employment terms by us, or (ii) in the event that we terminate the employment contract and the warrantholder has given us good reason to do so. The warrantholder will, however, be entitled to exercise vested warrants in the first exercise period after termination.

In the event that we terminate the employment contract and the warrantholder has not given us good reason to do so, the warrantholder may keep the right to continued vesting and exercise of warrants as if the employment was still in effect. In such case, any expense not yet recognized for the outstanding warrants is recognized immediately.

Warrants issued to consultants, advisors and board members only vest so long as the consultant, advisor or board member continues to provide services to us.

Exercise Periods

Vested warrants may be exercised during certain exercise periods each year. For 519,049 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 68,436 outstanding warrants granted in connection with our Preference D financing, there are four annual exercise periods that continue for 21 days following the day of publication of (i) our interim report (three-month report); (ii) the annual report notification—or if such notification is not published—the annual report; (iii) our interim report (six-month report); and (iv) our interim report (nine-month report). For these warrants, the last exercise period is 21 days following the publication of our interim report (nine-month report) in 2023. For 5,232,726 warrants granted on or after December 18, 2015, there are four annual exercise periods; each exercise period begins two full trading days after the publication of the public release of our earnings data of a fiscal quarter and continues until the end of the second-to-last trading day in which quarter the relevant earnings release is published. The warrants granted in December 2015 and later expire ten years after the grant date.

In the event of liquidation, a merger, a demerger, a sale or share exchange of more than 50% of our share capital, the warrantholders may be granted an extraordinary exercise period immediately prior to the transaction in which warrants may be exercised.

Warrants not exercised by the warrantholder during the last exercise period shall become null and void without further notice or compensation or payment of any kind to the warrantholder.

If the warrantholder is a consultant, advisor or board member, the exercise of warrants is conditional upon the warrantholder’s continued service to us at the time the warrants are exercised. If the consultant’s, advisor’s or board member’s relationship with us should cease without this being attributable to the warrantholder’s actions or omissions, the warrantholder shall be entitled to exercise vested warrants in the pre-defined exercise periods.

Adjustments

Warrantholders are entitled to an adjustment of the number of warrants issued and/or the exercise price applicable in the event of certain corporate changes. Events giving rise to an adjustment include, among other things, increases or decreases to our share capital at a price below or above market value, respectively, the issuance of bonus shares, changes in the nominal value of each share, and payment of dividends in excess of 10% of the Company's equity.

On January 13, 2015, in preparation for the Company's IPO, the shareholders decided at an extraordinary general meeting to issue bonus shares in the ratio of 3:1 of the Company's authorized, issued and outstanding ordinary and preference shares. The decision had a corresponding impact on the number of warrants issued and the exercise prices for outstanding warrants. Accordingly, the number of warrants was adjusted upwards in the ratio of 3:1 with a corresponding downward adjustment of the exercise prices in the ratio of 3:1. The effect of the bonus shares has been retrospectively reflected in all periods presented in these consolidated financial statements.

Warrant Activity

The following table specifies the number and weighted average exercise prices of and movements in warrants during the year:

	Total Warrants	Weighted Average Exercise Price EUR
Outstanding at January 1, 2017	**3,691,765**	**13.05**
Granted during the year	1,196,000	30.15
Exercised during the year (1)	(193,171)	8.49
Forfeited during the year	(73,440)	16.42
Expired during the year	—	—
Outstanding at December 31, 2017	**4,621,154**	**17.62**
Vested at the reporting date	**2,034,791**	**11.48**
Granted during the year	1,637,375	54.43
Exercised during the year (1)	(611,683)	10.82
Forfeited during the year	(35,217)	28.24
Expired during the year	—	—
Outstanding at December 31, 2018	**5,611,629**	**29.03**
Vested at the reporting date	**2,478,770**	**15.81**
Granted during the year	1,300,600	97.01
Exercised during the year (1)	(1,058,722)	16.33
Forfeited during the year	(33,296)	58.49
Expired during the year	—	—
Outstanding at December 31, 2019	**5,820,211**	**46.36**
Vested at the reporting date	**2,705,693**	**24.93**

(1) The weighted average share price (listed in $) at the date of exercise was €108.54, €58.01, and €26.75 for the financial years ended December 31, 2019, 2018 and 2017, respectively.

The following table specifies the weighted average exercise prices and weighted average remaining contractual life for outstanding warrants at December 31, 2019, per grant year.

	Number of Outstanding Warrants	Weighted Average Exercise Price EUR	Weighted Average Remaining Life (months)
Granted in 2012-2016	1,889,205	14.43	67
Granted in 2017	1,093,659	30.15	94
Granted in 2018	1,546,947	54.43	106
Granted in 2019	1,290,400	97.01	117
Outstanding at December 31, 2019	**5,820,211**	**46.36**	**94**

At December 31, 2019, the exercise prices of outstanding warrants under our warrant programs range from €6.48 to €107.14 depending on the grant dates. The range of exercise prices for outstanding warrants was €6.48 - €60.23, and €6.48 - €31.60, for the financial years ended December 31, 2018 and 2017, respectively.

The weighted average remaining life for outstanding warrants was 96 months and 112 months, for the financial years ended December 31, 2018 and 2017, respectively.

Warrant Compensation Costs

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

	2019	2018	2017
		(EUR'000)	
Research and development costs	22,357	10,225	4,775
General and administrative expenses	15,129	9,427	4,934
Total warrant compensation costs	**37,486**	**19,652**	**9,709**

Warrant compensation costs are determined with basis in the grant date fair value of the warrants granted and recognized over the vesting period. Fair value of the warrants is calculated at the grant dates by use of the Black-Scholes Option Pricing model with the following assumptions: (1) an exercise price equal to the estimated market price of our shares at the date of grant; (2) an expected lifetime of the warrants determined as a weighted average of the time from grant date to date of becoming exercisable and from grant date to expiry of the warrants; (3) a risk free interest rate equaling the effective interest rate on a Danish government bond with the same lifetime as the warrants; (4) no payment of dividends; and (5) a volatility for comparable companies for a historic period equaling the expected lifetime of the warrants. The expected volatility reflects the assumption that the historical volatility over a period similar to the life of the warrants is indicative of future trends. The expected volatility has been calculated using a simple average of daily historical data of comparable publicly traded companies, as we do not have sufficient data for the volatility of our own share price.

The following table summarizes the input to the Black-Scholes Option Pricing model and the calculated fair values for warrant grants in 2019, 2018 and 2017:

	2019	2018	2017
Expected volatility	52-54%	53 – 57%	54 – 60%
Risk-free interest rate	(0.77) – (0.05)%	(0.23) – 0.46%	(0.34) – 0.25%
Expected life of warrants (years)	5.05 – 7.10	5.05 – 7.14	5.05 – 7.10
Weighted average exercise price	€97.01	€54.43	€30.15
Fair value of warrants granted in the year	€27.24 – 55.64	€17.90 – 31.81	€9.65 – 17.29

Note 7—Finance Income and Finance Expenses

	2019	2018	2017
		(EUR'000)	
Interest income	10,056	4,020	923
Exchange rate gains	7,747	20,694	—
Total finance income	**17,803**	**24,714**	**923**
Interest expenses	207	127	97
Lease interest	1,014	—	—
Exchange rate losses	—	—	13,659
Total finance expenses	**1,221**	**127**	**13,756**

Interest income and interest expenses relate to financial assets and liabilities measured at amortized cost.

Note 8—Tax on Profit/(Loss) for the Year and Deferred Tax

	2019	2018	2017
		(EUR'000)	
Tax on profit/(loss) for the year:			
Current tax (expense)/income	234	394	477
	234	**394**	**477**
Tax for the year can be explained as follows:			
Profit/(loss) before tax	(218,250)	(130,491)	(124,374)
Tax at the Danish corporation tax rate of 22%	**48,015**	**28,708**	**27,362**
Tax effect of:			
Non-deductible costs	(8,249)	(4,327)	(1,553)
Additional tax deductions	10,875	4,074	356
Impact from associate	(1,680)	(2,383)	—
Tax credits	—	—	(1,028)
Other effects including effect of different tax rates	1,602	143	598
Deferred tax asset, not recognized	(50,329)	(25,821)	(25,258)
Tax on profit/(loss) for the year	**234**	**394**	**477**
Effective tax rate	**(0.11)%**	**(0.30)%**	**(0.38)%**

No changes to deferred tax have been recognized in the consolidated statement of profit or loss for 2019, 2018 or 2017.

	2019	2018	2017
		(EUR'000)	
Specification of Deferred Tax Assets			
Tax deductible losses	123,234	74,120	52,084
Other temporary differences	5,631	4,416	631
Deferred tax asset, not recognized	(128,865)	(78,536)	(52,715)
Total Deferred Tax Assets at December 31	**0**	**0**	**0**

Deferred tax assets have not been recognized in the consolidated statements of financial position due to uncertainty relating to future utilization. Deferred tax assets can be carried forward without timing limitations.

The Company had tax losses carried forward of €560.2 million, and €336.9 million at December 31, 2019 and December 2018, respectively, and relate to Danish entities. Tax losses can be carried forward infinitely, where certain limitations exist for amounts to be utilized each year.

Under Danish tax legislation, tax losses may be partly refunded by the tax authorities to the extent such tax losses arise from research and development activities. For the year ended December 31, 2019, the jointly taxed Danish entities had a negative taxable income, and accordingly were entitled to a tax refund of approximately €0.7 million, compared to approximately €0.7 million and €0.7 million for the years ended December 31, 2018 and 2017, respectively.

The parent company Ascendis Pharma A/S is jointly taxed with its Danish subsidiaries. The current Danish corporation tax is allocated between the jointly taxed Danish companies in proportion to their taxable income (full absorption with refunds for tax losses). These companies are taxed under the on-account tax scheme.

Note 9—Intangible Assets

	Goodwill (EUR'000)
Cost:	
At January 1, 2018	**3,495**
Additions	—
December 31, 2018	**3,495**
Additions	—
December 31, 2019	**3,495**
Accumulated impairment:	
At January 1, 2018	**—**
Impairment charge	—
At December 31, 2018	**—**
Impairment charge	—
At December 31, 2019	**—**
Carrying amount:	
At December 31, 2018	**3,495**
At December 31, 2019	**3,495**

Due to the risk associated with drug development, future income from development projects cannot be determined with sufficient certainty until the development activities have been completed and the necessary marketing approvals have been obtained. Accordingly, we do not recognize internally generated intangible assets at this time. Thus, all research and development costs incurred for the financial years ended December 31, 2019, 2018 and 2017, were recognized in the consolidated statement of profit or loss.

Goodwill relates to the acquisition of Complex Biosystems GmbH (now Ascendis Pharma GmbH) in 2007. Goodwill was calculated as the excess amount of the purchase price to the fair value of identifiable assets acquired, and liabilities assumed at the acquisition date. 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. Goodwill is tested for impairment on an annual basis at December 31, or more frequently, if indications of impairment are identified. There have been no impairments recognized in any of the periods presented.

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

Note 10—Property, Plant and Equipment

	Plant and Machinery	Other Equipment	Leasehold Improve-ments	Right-of-Use Assets	Total
			(EUR'000)		
Cost:					
At January 1, 2018	**4,507**	**1,641**	**650**	—	**6,798**
Additions	1,206	1,270	225	—	2,701
Disposals	(68)	(316)	—	—	(384)
At December 31, 2018	**5,645**	**2,595**	**875**	—	**9,115**
Adoption of IFRS 16 "Leases"	—	—	—	18,437	18,437
Additions	2,393	1,499	3,418	21,225	28,535
Disposals	—	(154)	(7)	—	(161)
Foreign exchange translation	—	4	2	457	463
At December 31, 2019	**8,038**	**3,944**	**4,288**	**40,119**	**56,389**
Accumulated depreciation:					
At January 1, 2018	**(3,054)**	**(854)**	**(333)**	—	**(4,241)**
Depreciation charge	(410)	(415)	(55)	—	(880)
Disposals	16	315	—	—	331
At December 31, 2018	**(3,448)**	**(954)**	**(388)**	—	**(4,790)**
Depreciation charge	(523)	(758)	(170)	(5,237)	(6,688)
Disposals	—	154	—	—	154
Foreign exchange translation	—	(5)	—	9	4
At December 31, 2019	**(3,971)**	**(1,563)**	**(558)**	**(5,228)**	**(11,320)**
Carrying amount:					
At December 31, 2018	**2,197**	**1,641**	**487**	—	**4,325**
At December 31, 2019	**4,067**	**2,381**	**3,730**	**34,891**	**45,069**

Included in leasehold improvements was an amount of €2.7 million, and €0.2 million related to expenditures for improvements under construction at December 31, 2019 and 2018, respectively. Of total additions regarding leaseholds improvements, €2.1 million and €0.0 million was unpaid at December 31, 2019 and 2018, respectively.

At December 31, 2019, the Company had non-cash additions on right-of-use assets of €39.0 million, which includes impact from implementing IFRS 16. For detailed information about our lease arrangements, please refer to Note 14.

Depreciations charges are specified below:

	2019	2018	2017
		(EUR'000)	
Research and development costs	5,282	827	701
General and administrative expenses	1,406	53	33
Total depreciation charges	**6,688**	**880**	**734**

Note 11—Investment in Associate

Visen Pharmaceuticals ("Visen") was formed in November 2018. The Company has granted Visen exclusive rights to develop and commercialize TransCon hGH, TransCon PTH and TransCon CNP in Greater China (the "Territory"), and as consideration for the granting of such rights has received a 50% ownership of Visen. The other investors contributed, in aggregate, $40.0 million in cash as their consideration for remaining 50% ownership.

Visen is a private entity not listed on any public exchange, with business activities within development, manufacturing and commercialization of endocrinology rare disease therapies in the Territory. The Company's interest in Visen is accounted for as an associate using the equity method in the consolidated financial statements as the Company has determined that it has significant influence but not joint control.

The following table illustrates the summarized relevant financial information of our investment in Visen:

Visen Pharmaceuticals	
Principal place of business	China
Ownership	50%

	2019	2018
	(EUR'000)	
Profit or loss		
Profit / (loss) for the year	(16,226)	(642)
Financial position		
Non-current assets	23,291	34,819
Current assets	32,446	34,155
Non-current liabilities	250	—
Current liabilities	1,667	9
Equity	53,820	68,965
Company's share of equity before eliminations	**26,910**	**34,483**
Elimination of internal profit recognized at December 31	*(11,372)*	*(17,400)*
Company's share of equity	**15,538**	**17,083**
Investment in associate at December 31	**15,538**	**17,083**

Revenue from Visen, recognized in the consolidated statement of profit or loss for 2019 and 2018, was €13.4 million and €10.5 million, respectively.

Trade receivable balance with Visen at December 31, 2019 and 2018 was €0.8 million and €0.0 million, respectively.

Visen requires the Company's consent to distribute dividends and incur indebtedness outside the normal course of business. At the reporting date, the Company has not given such consent.

Visen had no contingent liabilities or capital commitments as of December 31, 2019 or December 31, 2018. At the date these consolidated financial statements are authorized for use, no events have occurred after the reporting date that would influence the evaluation of these consolidated financial statements. Please refer to Note 21 regarding subsequent events.

Note 12—Share Capital

The share capital of Ascendis Pharma A/S consists of 47,985,837 fully paid shares at a nominal value of DKK 1, all in the same share class.

The number of shares of the Company are as follows:

	2019	2018	2017	2016	2015
Changes in share capital					
Beginning of year	42,135,448	36,984,292	32,421,121	25,128,242	16,935,780
Increase through cash contribution	5,850,389	5,151,156	4,563,171	7,292,879	8,192,462
End of year	**47,985,837**	**42,135,448**	**36,984,292**	**32,421,121**	**25,128,242**

Note 13—Distributable Equity

Share Premium Reserve

Share premium comprises the amounts received, attributable to shareholders' equity, in excess of the nominal amount of the shares issued at the parent company's capital increases, reduced by any expenses directly attributable to the capital increases. Under Danish legislation, share premium is an unrestricted reserve that is available to be distributed as dividends to a company's shareholders. Also, under Danish legislation, the share premium reserve can be used to offset accumulated deficits.

Foreign Currency Translation Reserve

Exchange rate differences relating to the translation of the results and net assets of our foreign operations and associate from their functional currencies to our presentation currency are recognized directly in other comprehensive income and accumulated in the foreign currency translation reserve. The foreign currency translation reserve is an unrestricted reserve that is available to be distributed as dividends to a company's shareholders.

Share-Based Payment Reserve

Warrants granted under our employee warrant program carry no rights to dividends and no voting rights. The share-based payment reserve represents the fair value of warrants recognized from grant date. Further details of the employee warrant program are provided in Note 6. Share-based payment reserve is an unrestricted reserve that is available to be distributed as dividends to a company's shareholders.

Retained Earnings or Accumulated Deficits

Retained earnings or accumulated deficits represent the accumulated profit or losses from the Company's operations. A positive balance of retained earnings is available to be distributed as dividends to a company's shareholders.

Note 14—Leases

The Company primarily leases office- and laboratory facilities. Lease arrangements contain a range of different terms and conditions and are typically entered into for fixed periods. Generally, the lease terms are between 2 and 10 years, and in addition, in order to improve flexibility to our operations, may provide us options to extend the lease or terminate the lease within the enforceable lease term. In our current lease portfolio, extension and termination options range between 1-6 years, in addition to the non-cancellable period.

We have implemented IFRS 16 by applying the modified retrospective approach. Accordingly, no comparative information is disclosed.

Leases Liabilities and Payments

Development in lease liabilities in 2019 are specified below:

	Beginning of period (1)	Additions	Accretion of interests	Cash out-flow	Foreign exchange translation (non-cash item)	End of period
			(EUR'000)			
Lease liabilities	17,700	21,240	1,014	(3,870)	535	36,619

(1) Beginning balance includes the impact from implementing IFRS 16, "Leases" at January 1, 2019.

Total cash outflow for leases in 2019 was €4.5 million which include prepaid leases at January 1, 2019 and at commencement date of new leases in 2019.

The maturity analysis of lease liabilities is disclosed in Note 17, "Financial Risk Management and Financial Instruments" in the section "Liquidity Risk Management".

Expenses Relating to Leases

The following expenses relating to lease activities are recognized in the consolidated statements of profit or loss:

	2019 (EUR'000)
Lease expenses	
Depreciations (research and development) (Note 10)	3,943
Depreciations (general and administration) (Note 10)	1,294
Expenses relating to short term leases and leases of low value assets	202
Lease interests (Note 7)	1,014
Total lease expenses	**6,453**

Note 15—Contract Liabilities

Deferred income was €0.9 million and €6.9 million for the financial years ended December 31, 2019 and 2018, respectively, and relate to partially satisfied performance obligations due to our ongoing research and development of licensed product candidates. The remaining balance of deferred income is expected to be recognized as revenue in 2020, as services are transferred.

Revenue recognized from deferred income was €6.1 million, €0.0 million and €0.0 million for the financial years ended December 31, 2019, 2018 and 2017, respectively.

Note 16—Other Commitments and Contingencies

Contractual commitments for the construction of leasehold improvements were €8.5 million and €0.0 million for the financial years ended December 31, 2019 and 2018, respectively.

With certain suppliers, the Company has agreed minimum commitments related to manufacturing of product supply, subject to continuous negotiation and adjustments according to the individual contractual terms and conditions. Delivery of product supply is recognized when the Company obtains control of the goods.

Of other contractual commitments, the Company has entered into short term leases and leases of low value equipment, and service contracts of various lengths in respect of research and development, IT- and facility related services. In addition, the Company's lease activities establish contractual commitments in relation to non-lease components which consists of utilities, maintenance, levies, and other services. Costs relating to those commitments are recognized as services are received.

Note 17—Financial Risk Management and Financial Instruments

Our financial assets and financial liabilities comprise the following:

	2019	2018
	(EUR'000)	
Financial assets		
Deposits	1,463	1,158
Receivables	804	6
Cash and cash equivalents	598,106	277,862
Financial assets measured at amortized cost	**600,373**	**279,026**
Financial liabilities		
Lease liabilities	36,619	—
Trade payables	27,765	19,740
Financial liabilities measured at amortized cost	**64,384**	**19,740**

Except for lease liabilities, the carrying amounts of the financial assets and financial liabilities are estimated being in line with the fair value due to the short-term (<1 year) nature of the balances.

Capital Management

We manage our capital to ensure that all group enterprises will be able to continue as going concern 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/accumulated deficits. We do not hold any external debt.

We are not subject to any externally imposed capital requirements. We review our capital structure on an ongoing basis. As we do not have external debt, such review currently comprises a review of the adequacy of our capital compared to the resources required for carrying out our activities.

Financial Risk Management Objectives

We regularly monitor the access to domestic and international financial markets, manage the financial risks relating to our operations, and analyze exposures to risk, including market risk, such as foreign 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 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

Our foreign exchange rate risks are unchanged to prior year. We are exposed to foreign exchange risks arising from various currency exposures, primarily with respect to the US Dollar, the British Pound and the Danish Krone.

Future milestone payments, which we are entitled to upon meeting underlying thresholds, are denominated in US Dollar. Further, the proceeds from our series D financing in November 2014, our IPO in February 2015 and our follow-on offerings, the latest being in March 2019, were in US Dollars. We seek to minimize our exchange rate risk by maintaining cash positions in the currencies in which we expect to incur the majority of our future expenses and we make payments from those reserves.

Foreign Currency Sensitivity Analysis

We are primarily exposed to US Dollars (USD), British Pounds (GBP), and Danish Kroner (DKK). There is an official target zone of 4.50% between DKK and EUR, which limits the likelihood of significant fluctuations between those two currencies in a short timeframe.

The following table details our sensitivity to a 10% increase and decrease in EUR against USD and GBP, respectively. 10% represents our assessment of the reasonably possible change in foreign currency rates. The sensitivity analysis includes only outstanding foreign currency denominated monetary items and adjusts their translation at the reporting date for a 10% change in foreign currency rate. A positive number indicates an increase in profit or loss, and equity before tax, while a negative number indicates the opposite. We believe the sensitivity analysis is representative of the inherent foreign exchange risk associated with our operations.

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

		Hypothetical impact on consolidated financial statements		
	Nominal positions	Increase in foreign exchange rate	Profit and loss before tax	Equity before tax
			(EUR '000)	
December 31, 2018				
USD/EUR	178,308	10%	17,831	17,831
GBP/EUR	(816)	10%	(82)	(82)

Interest Rate Risk Management

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

Credit Risk Management

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss. We consider all of our material counterparties to be creditworthy. Our exposure to credit risk is continuously monitored, in particular, if agreed payments are delayed.

While the concentration of credit risk is significant, we consider the credit risk for each of our individual counterparts to be low. Accordingly, since we had no significant trade receivables at December 31, 2019 or December 31, 2018, and our deposits are held with suppliers that are frequently used in our operations, we have made no provision for trade receivables or deposits.

Our maximum exposure to credit risk primarily relates to our cash and cash equivalents. The credit risk on cash and cash equivalents is limited because the counterparties, holding significant deposits, are banks with high credit-ratings assigned by international credit-rating agencies.

The banks are reviewed on a regularly basis and our deposits may be transferred during the year to mitigate credit risk.

We have considered the risk of expected credit loss over our cash deposits, including the hypothetical impact arising from the probability of default considering in conjunction with the expected loss given default from banks with similar credit rating and attributes. Our assessment did not reveal an expected material impairment loss, and accordingly we have made no provision for bank deposits.

Liquidity Risk Management

We manage our liquidity risk by maintaining adequate cash reserves and banking facilities, and by continuously monitoring our cash forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities. We monitor the risk of a shortage of funds using a liquidity planning tool, to ensure enough funds available to settle liabilities as they fall due.

Historically we have addressed the risk of insufficient funds through proceeds from our series D financing, our IPO, and our follow-on public offerings. The Company's Board of Directors has, at the time of approving the consolidated financial statements, a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future.

Maturity analysis for financial liabilities recognized in the consolidated statements of financial position at December 2019 are specified below. At December 2018, all financial liabilities recognized in the consolidated statements of financial position fell due within 12 months.

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

Note 18—Related Party Transactions

The Board of Directors and Executive Board (Key Management Personnel) are considered related parties as they have authorities and responsibilities with planning and directing our operations. Related parties also include undertakings in which such individuals have a controlling or joint controlling interest. Additionally, all our group enterprises and our associate are considered related parties.

Neither our related parties nor our major shareholders hold a controlling-, joint controlling-, or significant interest in the Group.

We have entered into employment agreements with and issued warrants to Key Management Personnel. In addition, we are paying fees for board tenure and board committee tenure to the independent members of our Board of Directors. Please refer to Note 6.

Transactions between the parent company and group enterprises comprise management and license fees, research & development services, and clinical supplies. These transactions have been eliminated in the consolidated financial statements. Transactions and outstanding balances with our associate Visen are disclosed in Note 11.

We have entered into indemnification agreements with our board members and members of our senior management.

Except for the information disclosed above, we have not undertaken any significant transactions with members of the Key Management Personnel, or undertakings in which the identified related parties have a controlling or joint controlling interest.

Note 19—Investments in Group Enterprises

Investments in Group enterprises comprise:

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

Associate	Domicile	Ownership
Visen Pharmaceuticals	Cayman Island	50%

Note 20—Ownership

The following investors, or groups of affiliated investors, are known by us to beneficially own more than 5% of our outstanding ordinary shares:

- T. Rowe Price Associates, Inc., USA
- Entities affiliated with FMR LLC, USA
- Entities affiliated with RA Capital Management, LLC, USA
- Entities affiliated with OrbiMed Private Investments V, L.P., USA
- Baker Bros. Advisors LP, 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 21—Subsequent Events

Coronavirus ("COVID-19") Outbreak

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 has spread around the world into a pandemic, including into countries where we have planned or have ongoing clinical trials, and countries where we rely on third parties to manufacture preclinical and clinical supplies, as well as commercial supply. If COVID-19 continues to spread in the United States and rest of the world, we may experience disruptions that could severely impact our business in many areas.

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

In addition, while we rely on third parties to manufacture preclinical and clinical supplies and materials, we can potentially experience delays in providing sufficient product supplies according to our planned and ongoing clinical trials. Further, if our product candidates are approved, we will need to secure sufficient manufacturing capacity with our third-party manufacturers to produce the quantities necessary to meet anticipated market demand. The COVID-19 pandemic, that currently impacts multiple jurisdictions worldwide, may impact the business of our existing or future manufacturers to perform their manufacturing obligations, which could have a negative impact on our operations.

We have assessed the COVID-19 outbreak impact on our consolidated financial statements, and since COVID-19 was not classified as an outbreak in 2019, the outbreak is considered a non-adjusting subsequent event, where any impact on the consolidated financial statement is accounted for subsequent to December 31, 2019. At the time these consolidated financial statements are authorized for issue, we have not found any adjustments necessary to the amounts recognized or disclosed in the consolidated financial statements.

At the time these consolidated financial statements are authorized for issue, we haven't identified significant disruptions to our clinical trial operations or identified any of our third-party manufacturers not being able to meet their obligations. However, while the global outbreak of COVID-19 continues to rapidly evolve, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be reliably predicted.

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

Item 19 Exhibits

The following exhibits are filed as part of this annual report:

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	Date	Number	File Number	
1.1	Articles of Association, currently in effect (English translation).	6-K	3/12/2020	1.1	001-36815	
2.1	Deposit Agreement dated January 27, 2015 among Ascendis Pharma A/S The Bank of New York Mellon and Owners and Holders of American Depositary Shares.	F-3	2/2/2016	4.2	333-209336	
2.2	Form of American Depositary Receipt (included in Exhibit 2.1).					
2.3	Description of Share Capital and American Depositary Shares					X
4.1(a)	Rental Agreement, between Technologiepark Heidelberg II GmbH & Co. KG and Ascendis Pharma GmbH (English translation).	F-1	12/18/2014	10.3(a)	333-201050	
4.1(b)	Supplement No. 1 to Rental Agreement, between Technologiepark Heidelberg II GmbH & Co. KG and Ascendis Pharma GmbH (English translation).	F-1	12/18/2014	10.3(b)	333-201050	
4.2(a)#	Reference is made to Exhibit 1.1.					
4.2(b)#	Form of Warrant Certificate for Warrants issued prior to December 2015.	F-1	12/18/2014	10.4(b)	333-201050	
4.2(c)#	Form of Warrant Certificate for Warrants issued since December 2015.	20-F	3/22/2017	4.4(c)	001-36815	
4.3#	Form of Indemnification Agreement for board members and senior management.	F-1	1/16/2015	10.5	333-201050	
4.4(a)	Registration Rights Agreement dated November 24, 2014 among Ascendis Pharma A/S and the investors set forth therein.	F-1	12/18/2014	10.6	333-201050	
4.4(b)	First Amendment to Registration Rights Agreement dated December 11, 2015 by and among Ascendis Pharma A/S and the investors set forth therein.	6-K	12/14/2015	4.2	001-36815	
4.5	Registration Rights Agreement dated December 11, 2015 by and among Ascendis Pharma A/S, Fidelity Securities Fund: Fidelity Series Small Cap Opportunities Fund—Healthcare Sub and Fidelity Stock Selector Small Cap Fund—Health Care Sub.	6-K	12/14/2015	4.1	001-36815	
4.6	Lease Agreement dated September 7, 2015 between Ascendis Pharma A/S and Dades AS.	F-3	2/2/2016	10.1	001-36815	
4.7†	Manufacturing and Supply Agreement dated December 21, 2017, between Ascendis Pharma A/S and NOF Corporation.	20-F	3/28/2018	4.9	001-36815	
4.8†	Manufacturing and Supply Agreement dated January 12, 2017, between Ascendis Pharma A/S and Medicom Innovation Partner a/s.	20-F	3/28/2018	4.10	001-36815	
4.9*	Supply Agreement dated January 1, 2019, between Ascendis Pharma A/S and Vetter Pharma International GMBH.	20-F	4/3/2019	4.11	001-36815	
4.10*	Manufacturing and Supply Agreement dated October 28, 2018, between Ascendis Pharma A/S and Carbogen Amcis AG.	20-F	4/3/2019	4.12	001-36815	

4.11*	Commercial Supply Agreement dated January 9, 2019, between Ascendis Pharma A/S and Fujifilm Diosynth Biotechnologies UK Limited.	20-F	4/3/2019	4.13	001-36815	
4.12*	Shareholders Agreement dated November 7, 2018, by and among Ascendis Pharma A/S and the parties set forth therein.	20-F	4/3/2019	4.14	001-36815	
4.13*	Exclusive Licence Agreement dated November 7, 2018, between Ascendis Pharma Endocrinology Division A/S and Visen Pharmaceuticals (CNP).	20-F	4/3/2019	4.15	001-36815	
4.14*	Exclusive Licence Agreement dated November 7, 2018, between Ascendis. Pharma Endocrinology Division A/S and Visen Pharmaceuticals (hGH).	20-F	4/3/2019	4.16	001-36815	
4.15*	Exclusive Licence Agreement dated November 7, 2018, between Ascendis Pharma Endocrinology Division A/S and Visen Pharmaceuticals (PTH).	20-F	4/3/2019	4.17	001-36815	
4.16*	Tech Transfer and Manufacturing Services Agreement dated December 12, 2019 between Ascendis Pharma A/S and Lonza Ltd.					X
4.17*	Multi-Year Packaging Agreement dated December 1, 2019 between Ascendis Pharma A/S and Sharp Corporation.					X
8.1	List of Subsidiaries.					X
12.1	Certification by Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
12.2	Certification by Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
13.1	Certification by Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
13.2	Certification by Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
15.1	Consent of Independent Registered Public Accounting Firm.					X
EX-101.INS	XBRL Instance Document.					X
EX-101.SCH	XBRL Taxonomy Extension Schema Document.					X
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
EX-101.IAB	XBRL Taxonomy Extension Labels Linkbase Document.					X
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

† Confidential treatment has been granted for certain information contained in this Exhibit. Such information has been omitted and filed separately with the SEC.

# Indicates senior management contract or compensatory plan.

* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10). Such omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

Signatures

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Ascendis Pharma A/S

By: /s/ Jan Møller Mikkelsen
Jan Møller Mikkelsen
President, Chief Executive Officer, Board Member and Executive Director (Principal Executive Officer)

Date: April 2, 2020

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

Date: April 2, 2020

Exhibit 2.3

DESCRIPTION OF SHARE CAPITAL

Set forth below is a summary of certain information concerning our share capital as well as a description of certain provisions of our articles of association, the registration rights agreement entered into in December 2014 to which we and certain shareholders are parties, as amended, or the 2014 Registration Rights Agreement, the registration rights agreement entered into in December 2015 to which we and certain holders of American Depositary Shares, also referred to as ADSs, are parties or the 2015 Registration Rights Agreement, and relevant provisions of the Danish Companies Act (in Danish: Selskabsloven). Because the following is only a summary, it does not contain all of the information that may be important to you. The summary includes certain references to and descriptions of material provisions of our articles of association, the 2014 Registration Rights Agreement, the 2015 Registration Rights Agreement and Danish law in effect as of the date of our Annual Report on Form 20-F. The summary below does not purport to be complete and is qualified in its entirety by reference to applicable Danish Law and our articles of association, the 2014 Registration Rights Agreement and the 2015 Registration Rights Agreement, copies of which are incorporated by reference into our Annual Report on Form 20-F. Further, please note that ADS holders are not treated as our shareholders and do not have rights as a shareholder. For more information regarding the rights of ADS holders, see the section of this exhibit titled "Description of American Depositary Shares".

General

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

Authorizations to our board of directors

As of December 31, 2019, our board of directors is authorized to increase the share capital as follows:

- Our board of directors is authorized to increase our share capital by up to 9,000,000 shares without pre-emptive subscription rights for existing shareholders in connection with cash contributions, debt conversion and contributions in kind, provided, however, that the capital increases are carried out at market value. This authorization is valid until May 28, 2024.

- Our board of directors is authorized to increase our share capital by up to 9,000,000 shares with pre-emptive subscription rights for existing shareholders in connection with cash contributions, provided, however, that the capital increases are carried out at market value. This authorization is valid until May 28, 2024.

- Our board of directors is authorized to issue an additional 1,237,525 warrants and to increase our share capital by up to 1,237,525 shares without pre-emptive subscription rights for existing shareholders in connection with the exercise, if any, of said warrants and to determine the terms and conditions thereof. Our board of directors cannot issue warrants pursuant to this authorization to the extent that already issued and still outstanding warrants under this authorization amount to 20% or more of our share capital. This authorization is valid until May 28, 2023.

- Our board of directors is, without pre-emptive rights for the existing shareholders, authorized to obtain loans against issuance of convertible notes which confer the right to subscribe up to 9,000,000 shares. The convertible notes shall be offered at a subscription price and a conversion price that correspond in aggregate to at least the market price of the shares at the time of the decision of our board of directors to issue the convertible notes. The loans shall be paid in cash and our board of directors shall determine the terms and conditions for the convertible notes. This authorization is valid until May 28, 2024.

- Our board of directors is authorized at one or more times to increase the Company's share capital in favor of its employees and the employees of its subsidiaries with up to nominal DKK 500,000 without pre-emptive subscription rights for the Company's shareholders. This authorization is valid until May 23, 2021.

If our board of directors exercises its authorizations in full, and all warrants and convertible debt instruments are exercised fully (not including already issued warrants), then our share capital will amount to 76,723,362 shares consisting of 76,723,362 shares with a nominal value of DKK 1 each.

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

Our warrants

Our employees, consultants, advisors and board members are eligible to participate in our warrant incentive program. Warrants have been issued by the general meeting or by our board of directors pursuant to valid authorizations in our articles of association and the terms and conditions have, in accordance with the Danish Companies Act, been incorporated in our articles of association as in effect from time to time. Each warrant grants the holder the right to subscribe for one ordinary share against cash payment

of the exercise price. The exercise price is determined by our board of directors and historically has not been less than the estimated fair value of our ordinary shares on the date of grant. Our board of directors is authorized to issue an additional 1,237,525 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. As of December 31, 2019, there were outstanding 5,820,211 warrants to subscribe for our ordinary shares and such warrants had a weighted average exercise price of €46.36.

The grant of warrants to any participant is at the discretion of our board of directors and based on the recommendation of our management. The board of directors may determine the terms and conditions of the warrants issued, including exercise periods, subscription price and adjustments caused by changes to our company's situation. Warrantholders are entitled to an adjustment of the number of warrants issued and/or the exercise price applicable in the event of certain corporate changes. Events giving rise to an adjustment include, among other things, increases or decreases to our share capital at a price below or above market value, respectively, the issuance of bonus shares, changes in the nominal value of each share, and payment of dividends in excess of 10% of the Company's equity. For the purpose of implementing the capital increases necessary in connection with the exercise of warrants, our board of directors has been authorized to increase our share capital by one or more issuances of shares with a total nominal value corresponding to the number of warrants issued upon cash payment of the exercise price without any pre-emptive subscription rights to existing shareholders.

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

Vested warrants may be exercised during certain exercise periods each year. For 519,049 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 68,436 outstanding warrants granted in connection with our preference D financing, there are four annual exercise periods that continue for 21 days following the day of publication of (i) our interim report (three-month report); (ii) the annual report notification—or if such notification is not published—the annual report; (iii) our interim report (six-month report); and (iv) our interim report (nine-month report). For these warrants, the last exercise period is 21 days following the publication of our interim report (nine-month report) in 2023. For 5,232,726 outstanding warrants granted on or after December 18, 2015, there are four annual exercise periods; each exercise period begins two full trading days after the publication of the public release of our earnings data of a fiscal quarter and continues until the end of the second-to-last trading day in which quarter the relevant earnings release is published. The warrants granted on or after December 18, 2015 expire ten years after the grant date.

Registration rights

Under the 2014 Registration Rights Agreement, as of December 31, 2019, the owners of approximately 7.7 million of our ordinary shares (or ADSs representing such shares) or their transferees, have the right to require us to register their shares under the Securities Act of 1933, as amended, or the Securities Act, so that those shares or ADSs may be publicly resold, or to include their shares or ADSs in certain registration statements we file, in each case as described below.

Under the 2015 Registration Rights Agreement, we were required to timely register with the SEC 1.0 million ordinary shares underlying 1.0 million ADSs (the "Fidelity Shares"), purchased by Fidelity Securities Fund: Fidelity Series Small Cap Opportunities Fund—Healthcare Sub and Fidelity Stock Selector Small Cap Fund—Health Care Sub on December 14, 2015.

In accordance with our obligations under the 2015 Registration Rights Agreement and the 2014 Registration Rights Agreement, we filed a resale registration statement in February 2016 to register for resale the Fidelity Shares and ordinary shares owned by certain of the parties to the 2014 Registration Rights Agreement.

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

Form F-3 registration rights

Under the 2014 Registration Rights Agreement, as of December 31, 2019, the owners of approximately 7.7 million of our ordinary shares (or ADSs representing such shares) or their transferees, are entitled to certain Form F-3 registration rights. The holders of at least 25% of these shares can make a request that we register their ordinary shares on a registration statement on Form F-3 if we are eligible to file a registration statement on Form F-3 and if the aggregate price to the public of the shares or ADSs offered is at least $5.0 million (net of underwriting discounts and commissions and certain expenses). Additionally, we will not be required to effect a Form F-3 registration (i) during the period beginning 30 days prior to the filing and ending 90 days following the effectiveness of a Company-initiated registration statement or (ii) more than twice within a twelve-month period.

In addition, the owners of the Fidelity Shares are entitled to registration of the Fidelity Shares on Form F-3 as described herein under the caption "Registration Rights."

Piggyback registration rights

Under the 2014 Registration Rights Agreement, as of December 31, 2019, in the event that we determine to register any of our securities under the Securities Act (subject to certain exceptions), either for our own account or for the account of other security holders, the owners of approximately 8.0 million of our ordinary shares or their transferees, will be entitled to certain "piggyback" registration rights allowing the holders to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related to employee benefit plans, the offer and sale of debt securities, or corporate reorganizations or certain other transactions, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration. In an underwritten offering, the managing underwriter, if any, has the right to limit the number of shares such holders may include.

Expenses of registration

Under the 2014 Registration Rights Agreement, we agreed to pay certain registration expenses of the holders of the shares registered pursuant to the Form F-3 and piggyback registration rights described above, including the expenses of one counsel for the selling holders.

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

Expiration of registration rights

Under the 2014 Registration Rights Agreement, the Form F-3 and piggyback registration rights described above will expire, with respect to any particular shareholder, upon the earlier of a change in control event, five years after the consummation of our initial public offering or when that shareholder can sell all of its shares (or ADSs representing such shares) under Rule 144 or Regulation S of the Securities Act during any three-month period.

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

Owners' register

We are obligated to maintain an owners' register (in Danish: *ejerbog*). The owners' register is maintained by Computershare A/S (Company Registration (CVR) no. 27088899), our Danish share registrar and transfer agent. It is mandatory that the owners' register is maintained within the European Union and that it is available to public authorities.

Pursuant to the Danish Companies Act, public and private limited liability companies are required to register with the Danish Business Authority information regarding shareholders who own at least 5% of the share capital or the voting rights. Pursuant to this provision, we file registrations with the Public Owners' Register of the Danish Business Authority. Shareholders that exceed the ownership threshold must notify us and we will subsequently file the information with the Danish Business Authority. Reporting is further required upon reaching thresholds of 10%, 15%, 20%, 25%, 33 1/3%, 50%, 66 2/3%, 90% and 100%.

Articles of association and Danish corporate law

With respect to our articles of association, the following should be emphasized:

Objects clause

Our corporate object, as set out in article 3 of our articles of association, is to develop ideas and preparations for the combating of disease medically, to manufacture and sell such preparations or ideas, to own shares of companies with the same objects and to perform activities in natural connection with these objects.

Summary of provisions regarding the board of directors and the executive board

Pursuant to our articles of association, our board of directors shall be elected by our shareholders at the general meeting and shall be composed of not less than three and no more than 10 members. With respect to the duration of the term which our board members severally hold office, the board of directors is classified into two classes as nearly equal in number as possible. Such classes consist of one class of directors ("Class II") who were elected at the annual general meeting held in 2018 for a term expiring at the annual general meeting to be held in 2020; and a second class of directors ("Class I") who were elected at the annual general meeting held in 2019 for a term expiring at the annual general meeting to be held in 2021. The shareholders shall increase or decrease the number of directors, in order to ensure that the two classes shall be as nearly equal in number as possible; provided, however, that no decrease shall have the effect of shortening the term of any other director. At each annual general meeting, the successors of the class of directors whose term expires at that meeting shall be elected to hold office for a term expiring at the annual general meeting held in the second year following the year of their election. Board members must retire from the board of directors at the annual general meeting following their 75th birthday. Board members are not required to own any shares of our share capital.

The board of directors shall appoint and employ an executive board consisting of one to five members to attend to our day-to-day management, and the board of directors shall determine the terms and conditions of the employment.

Voting rights

Each shareholder is entitled to one vote for each share owned at the time of any general meeting. As compared with Danish citizens, there are no limitations under the articles of association or under Danish law on the rights of foreigners or non-Danish citizens to hold or vote our shares.

Dividend rights

Our shareholders may at general meetings authorize the distribution of ordinary and extraordinary dividends. Our shareholders may not distribute dividends in excess of the recommendation from our board of directors and may only pay out dividends from our distributable reserves, which are defined as results from operations carried forward and reserves that are not bound by law after deduction of loss carried forward.

Our shareholders are eligible to receive any dividends declared and paid out. However, we have not to date declared or paid any dividends and we currently intend to retain all available financial resources and any earnings generated by our operations for use in the business and we do not anticipate paying any dividends in the foreseeable future. The payment of any dividends in the future will depend on a number of factors, including our future earnings, capital requirements, financial condition and future prospects, applicable restrictions on the payment of dividends under Danish law and other factors that our board of directors may consider relevant.

See the section titled "*Item 10 E. Additional Information—Taxation*" in our Annual Report on Form 20-F for a summary of certain tax consequences in respect of dividends or distributions to holders of our ordinary shares or the ADSs.

Pre-emptive subscription rights

Under Danish law, all shareholders have pre-emptive subscription rights in connection with capital increases that are carried out as cash contributions. An increase in share capital can be resolved by the shareholders at a general meeting or by the board of directors pursuant to an authorization given by the shareholders. In connection with an increase of a company's share capital, the shareholders may, by resolution at a general meeting, approve deviations from the general Danish pre-emptive rights of the shareholders. Under the Danish Companies Act, such resolution must be adopted by the affirmative vote of shareholders holding at least a two-thirds majority of the votes cast and the share capital represented at the general meeting.

The board of directors may resolve to increase our share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations set forth above under the caption "Authorizations to Our Board of Directors."

Unless future issuances of new shares and/or pre-emptive rights are registered under the Securities Act or with any authority outside Denmark, U.S. shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights.

Rights on liquidation

Upon a liquidation or winding-up of our company, shareholders will be entitled to participate, in proportion to their respective shareholdings, in any surplus assets remaining after payment of our creditors.

Limitations on holding of shares

There are no limitations on the right to hold shares under the articles of association or Danish law.

Liability to capital calls by us

Under our articles of association as well as the Danish Companies Act, our shareholders are not obligated to pay further amounts to us. All our shares are fully-paid.

Sinking fund provisions

There are no sinking fund provisions or similar obligations relating to our ordinary shares.

Disclosure requirements

Pursuant to Section 55 of the Danish Companies Act, a shareholder is required to notify us when such shareholder's stake represents 5% or more of the voting rights in our company or the nominal value accounts for 5% or more of the share capital, and when a change of a holding already notified entails that the limits of 5%, 10%, 15%, 20%, 25%, 50%, 90% or 100% and the limits of one-third and two-thirds of the share capital's voting rights or nominal value are reached or are no longer reached. The notification shall be given within two weeks following the date when the limits are reached or are no longer reached.

The notification shall provide information about the full name, address or, in the case of undertakings, registered office, the number of shares and their nominal value and share classes as well as information about the basis on which the calculation of the holdings has been made. In the event that the shareholder is a non-resident company or citizen of Denmark, the notification shall include documentation, which clearly identifies the owner. The company shall cause the notification to be entered in the owners' register.

Upon the implementation of adopted legislation in Denmark, we will be obligated to collect and store for a period of at least five years certain information regarding the beneficial owners of shares in the Company. A beneficial owner is a physical person that directly or indirectly controls a shareholder. The Company shall cause such information to be registered with the Danish Business Authority.

The legal status of the notification obligations is not fully clarified in relation to ADS holders and an ADS holder may be subject to such obligations.

General meetings

The general meeting of shareholders is the highest authority in all matters, subject to the limitations provided by Danish law and the articles of association. The annual general meeting shall be held in the Greater Copenhagen area not later than the end of May in each year.

At the annual general meeting, the audited annual report is submitted for approval, together with the proposed appropriations of profit/treatment of loss, the election of the board of directors and election of our auditors. In addition, the board of directors reports on our activities during the past year.

General meetings are convened by the board of directors with a minimum of two weeks' notice and a maximum of four weeks' notice by letter, fax or by e-mail. A convening notice will also be forwarded to shareholders recorded in our owners' register, who have requested such notification and by publication in the Danish Business Authority's computerized information system and on the company's website.

At the latest, two weeks before a general meeting (inclusive of the day of the general meeting), we shall make the following information and documents available on our webpage:

- the convening notice,

- the documents that shall be presented at the general meeting, and

- the agenda and the complete proposals.

Shareholders are entitled to attend general meetings, either in person or by proxy, and they or their proxy may be accompanied by one advisor. A shareholder's right to attend general meetings and to vote at general meetings is determined on the basis of the shares that the shareholder holds on the registration date. The registration date shall be one week before the general meeting is held. The shares which the individual shareholder holds are calculated on the registration date on the basis of the registration of ownership in the owners' register as well as notifications concerning ownership which the Company has received with a view to update the ownership in the owners' register. In addition, any shareholder who is entitled to attend a general meeting and who wishes to attend must have requested an admission card from us no later than three days in advance of the general meeting. Any shareholder is entitled to submit proposals to be discussed at the general meetings. However, proposals by the shareholders to be considered at the annual general meeting must be submitted in writing to the board of directors not later than six weeks before the annual general meeting.

Extraordinary general meetings must be held upon resolution of an annual general meeting to hold such a meeting or upon request of the board of directors, our auditors or shareholders representing at least 1/20 of the registered share capital or such lower percentage as our articles of association may provide. Our articles of association do not state such lower percentage.

Holders of ADSs are not entitled to directly receive notices or other materials or to attend or vote at general meetings.

Resolutions in general meetings

Resolutions made by the general meeting generally may be adopted by a simple majority of the votes cast, subject only to the mandatory provisions of the Danish Companies Act and our articles of association. Resolutions concerning all amendments to the articles of association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder's ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose or increase any obligations of the shareholders towards the company require unanimity.

Quorum requirements

There are no quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares.

Squeeze out

According to Section 70 of the Danish Companies Act, shares in a company may be redeemed in full or in part by a shareholder holding more than nine-tenths of the shares and the corresponding voting rights in the company. Furthermore, according to Section 73 of the Danish Companies Act, a minority shareholder may require a majority shareholder holding more than nine-tenths of the shares and the corresponding voting rights to redeem the minority shareholder's shares.

Danish rules intended to prevent market abuse

As of July 3, 2016, EU Regulation No 596/2014 on market abuse entered into force and Chapter 10 of the Danish Securities Trading Act was repealed. Pursuant to said Chapter 10, we had adopted an internal code on inside information in respect of the holding of and carrying out of transactions by our board of directors and executive officers and employees in the shares or ADSs or in financial instruments the value of which is determined by the value of the ordinary shares or ADSs, and we had drawn up a list of those persons working for us who could have access to inside information on a regular or incidental basis and had informed such persons of the rules on insider trading and market manipulation, including the sanctions which could be imposed in the event of a violation of those rules. However, said EU Regulation No 596/2014 on market abuse imposes no such requirements on us and we have therefore taken steps to abandon our previous practice.

Limitation on liability

Under Danish law, members of the board of directors or senior management may be held liable for damages in the event that loss is caused due to their negligence. They may be held jointly and severally liable for damages to the company and to third parties for acting in violation of the articles of association and Danish law.

According to the Danish Companies Act, the general meeting is allowed to discharge our board members and members of our senior management from liability for any particular financial year based on a resolution relating to the financial statements. This

discharge means that the general meeting will discharge such board members and members of our senior management from liability to us; however, the general meeting cannot discharge any claims by individual shareholders or other third parties.

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

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

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

Comparison of Danish corporate law and our articles of association and Delaware corporate law

The following comparison between Danish corporate law, which applies to us, and Delaware corporate law, the law under which many publicly traded companies in the United States are incorporated, discusses additional matters not otherwise described in this exhibit. This summary is subject to Danish law, including the Danish Companies Act, and Delaware corporate law, including the Delaware General Corporation Law. Further, please note that ADS holders will not be treated as our shareholders and will not have any shareholder rights.

Duties of board members

Denmark. Public limited liability companies in Denmark are usually subject to a two-tier governance structure with the board of directors having the ultimate responsibility for the overall supervision and strategic management of the company in question and with an executive board/management being responsible for the day-to-day operations. Each board member and member of the executive board/management is under a fiduciary duty to act in the interest of the company, but shall also take into account the interests of the creditors and the shareholders. Under Danish law, the members of the board of directors and executive management of a limited liability company are liable for losses caused by negligence whether shareholders, creditors or the company itself suffers such losses. They may also be liable for wrongful information given in the annual financial statements or any other public announcements from the company. An investor suing for damages is required to prove its claim with regard to negligence and causation. Danish courts, when assessing negligence, have been reluctant to impose liability unless the directors and officers neglected clear and specific duties. This is also the case when it comes to liability with regard to public offerings or liability with regard to any other public information issued by the company.

Delaware. The board of directors bears the ultimate responsibility for managing the business and affairs of a corporation. In discharging this function, directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. Delaware courts have decided that the directors of a Delaware corporation are required to exercise informed business judgment in the performance of their duties. Informed business judgment means that the directors have informed themselves of all material information reasonably available to them. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

Terms of the members of our board of directors

Denmark. Under Danish law, the members of the board of directors of a limited liability company are generally appointed for an individual term of one year. There is no limit on the number of consecutive terms the board members may serve. Pursuant to our articles of association, our board members are appointed by the general meeting of shareholders for a term of two years and are divided into two classes. Election of board members is, according to our articles of association, an item that shall be included on the agenda for the annual general meeting.

At the general meeting, shareholders are entitled at all times to dismiss a board member by a simple majority vote.

It follows from Section 140 of the Danish Companies Act that in limited liability companies that have employed an average of at least 35 employees in the preceding three years, the employees are entitled to elect a minimum of two representatives and

alternate members to the company's board of directors up to one half the number of the shareholder elected directors. If the number of representatives to be elected by the employees is not a whole number, such number must be rounded up.

Our company currently employs more than an average of 35 employees and has done so since 2016. Consequently, from 2018, our employees have been entitled to demand representation on our board of directors. The question will, upon request from the employees, be put to a popular vote among the employees. If more than half of the employees (regardless whether they participate in the vote) vote in favor of having representation, we must organize an election process.

Additionally, Section 141 of the Danish Companies Act allows for group representation on the board of directors of our Company, *i.e.* that employees of our Danish subsidiaries may demand representation on our board. However, our Danish subsidiaries do not currently have employees. The employees of Ascendis Pharma, Inc., and the employees of our other foreign subsidiary, Ascendis Pharma GmbH, may only demand representation on our board of directors provided that our general meeting adopts a resolution to that effect.

Delaware. The Delaware General Corporation Law generally provides for a one-year term for directors, but permits directorships to be divided into up to three classes, of relatively equal size, with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the stockholders. A director elected to serve a term on a "classified" board may not be removed by stockholders without cause. There is no limit in the number of terms a director may serve.

Board member vacancies

Denmark. Under Danish law, in the event of a vacancy, new board members are elected by the shareholders in a general meeting. Thus, a general meeting will have to be convened to fill a vacancy on the board of directors. However, the board of directors may choose to wait to fill vacancies until the next annual general meeting of the company, provided that the number of the remaining board members is more than two, and provided that the remaining board members can still constitute a quorum. It is only a statutory requirement to convene a general meeting to fill vacancies if the number of remaining members on the board is less than three.

Delaware. The Delaware General Corporation Law provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (1) otherwise provided in the certificate of incorporation or bylaws of the corporation or (2) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Conflict-of-interest transactions

Denmark. Under Danish law, board members may not take part in any matter or decision-making that involves a subject or transaction in relation to which the board member has a conflict of interest with us.

Delaware. The Delaware General Corporation Law generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- the material facts as to the director's relationship or interest are disclosed and a majority of disinterested directors' consent;
- the material facts are disclosed as to the director's relationship or interest and a majority of shares entitled to vote thereon consent; or
- the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the stockholders.

Proxy voting by board members

Denmark. In the event that a board member in a Danish limited liability company is unable to participate in a board meeting, the elected alternate, if any, shall be given access to participate in the board meeting. Unless the board of directors has decided otherwise, or as otherwise is set out in the articles of association, the board member in question may grant a power of attorney to another board member, provided that this is considered safe considering the agenda in question.

Delaware. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Shareholder rights

Notice of meeting

Denmark. According to the Danish Companies Act, general meetings in limited liability companies shall be convened by the board of directors with a minimum of two weeks' notice and a maximum of four weeks' notice as set forth in the articles of association. A convening notice shall also be forwarded to shareholders recorded in our owners' register, who have requested such notification. There are specific requirements as to the information and documentation required to be disclosed in connection with the convening notice.

Delaware. Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.

Voting rights

Denmark. Each ordinary share confers the right to cast one vote at the general meeting of shareholders, unless the articles of association provide otherwise. Each holder of ordinary shares may cast as many votes as it holds shares. Shares that are held by us or our direct or indirect subsidiaries do not confer the right to vote.

Delaware. Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event can a quorum consist of less than one third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than ten days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

Shareholder proposals

Denmark. According to the Danish Companies Act, extraordinary general meetings of shareholders will be held whenever our board of directors or our appointed auditor requires. In addition, one or more shareholders representing at least 1/20th of the registered share capital of the company may, in writing, require that a general meeting be convened. If such a demand is forwarded, the board of directors shall convene the general meeting within two weeks thereafter.

All shareholders have the right to present proposals for adoption at the annual general meeting, provided that the proposals are forwarded at the latest six weeks prior thereto. In the event that the proposal is received at a later date, the board of directors will decide whether the proposal has been forwarded in due time to be included on the agenda.

Delaware. Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting of stockholders. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least $2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

Action by written consent

Denmark. Under Danish law, it is permissible for shareholders to take action and pass resolutions by written consent in the event of unanimity; however, this will normally not be the case in listed companies and for a listed company, this method of adopting resolutions is generally not feasible.

Delaware. Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

Appraisal rights

Denmark. The concept of appraisal rights does not exist under Danish law, except in connection with statutory redemptions rights according to the Danish Companies Act.

According to Section 73 of the Danish Companies Act, a minority shareholder may require a majority shareholder that holds more than 90% of the company's registered share capital and votes to redeem his or her shares. Similarly, a majority shareholder holding more than 90% of the company's share capital and votes may, according to Section 70 of the same act, squeeze out the minority shareholders. In the event that the parties cannot agree to the redemption squeeze out price, this shall be determined by an independent evaluator appointed by the court. Additionally, there are specific regulations in Sections 249, 267, 285 and 305 of the Danish Companies Act that require compensation in the event of national or cross-border mergers and demergers. Moreover, shareholders who vote against a cross-border merger or demerger are, according to Sections 286 and 306 of the Danish Companies Act, entitled to have their shares redeemed.

Delaware. The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

Shareholder suits

Denmark. Under Danish law, only a company itself can bring a civil action against a third party; an individual shareholder does not have the right to bring an action on behalf of a company. An individual shareholder may, in its own name, have an individual right to take action against such third party in the event that the cause for the liability of that third party also constitutes a negligent act directly against such individual shareholder.

Delaware. Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

Repurchase of shares

Denmark. Danish limited liability companies may not subscribe for newly issued shares in their own capital. Such company may, however, according to the Danish Companies Act Sections 196-201, acquire fully paid shares of its own capital, provided that the board of directors has been authorized thereto by the shareholders acting in a general meeting. Such authorization can only be given for a maximum period of five years and the authorization shall fix (i) the maximum value of the shares and (ii) the minimum and the highest amount that the company may pay for the shares. Shares may generally only be acquired using distributable reserves.

Delaware. Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

Anti-takeover provisions

Denmark. Under Danish law, it is possible to implement limited protective anti-takeover measures. Such provisions may include, among other things, (i) different share classes with different voting rights, (ii) specific requirements to register the shares named in the company's owners register and (iii) notification requirements concerning participation in general meetings. We have currently not adopted any such provisions.

Delaware. In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits "business combinations," including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation's voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transaction;

- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or

- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until 12 months following its adoption.

Inspection of books and records

Denmark. According to Section 150 of the Danish Companies Act, a shareholder may request an inspection of the company's books regarding specific issues concerning the management of the company or specific annual reports. If approved by shareholders with simple majority, one or more investigators are elected. If the proposal is not approved by simple majority but 25% of the share capital votes in favor, then the shareholder can request the court to appoint an investigator.

Delaware. Under the Delaware General Corporation Law, any stockholder may inspect certain of the corporation's books and records, for any proper purpose, during the corporation's usual hours of business.

Pre-emptive rights

Denmark. Under Danish law, all shareholders have pre-emptive subscription rights in connection with capital increases that are carried out as cash contributions. In connection with an increase of a company's share capital, the shareholders may, by resolution at a general meeting, approve deviations from the general Danish pre-emptive rights of the shareholders. Under the Danish Companies Act, such resolution must be adopted by the affirmative vote of shareholders holding at least a two-thirds majority of the votes cast and the share capital represented at the general meeting. The board of directors may resolve to increase our share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations described above under the caption "Authorizations to Our Board of Directors."

Unless future issuances of new shares are registered under the Securities Act or with any authority outside Denmark, U.S. shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights.

Delaware. Under the Delaware General Corporation Law, stockholders have no pre-emptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

Dividends

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

Delaware. Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of shares, property or cash.

Shareholder vote on certain reorganizations

Denmark. Under Danish law, all amendments to the articles of association shall be approved by the general meeting of shareholders with a minimum of two-thirds of the votes cast and two-thirds of the represented share capital. The same applies to solvent liquidations, mergers with the company as the discontinuing entity, mergers with the company as the continuing entity if shares are issued in connection therewith and demergers. Under Danish law, it is debatable whether the shareholders must approve a decision to sell all or virtually all of the company's business/assets.

Delaware. Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

However, under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, unless required by the certificate of incorporation, if (1) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (2) the shares of stock of the surviving corporation are not changed in the merger and (3) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

Amendments to governing documents

Denmark. All resolutions made by the general meeting may be adopted by a simple majority of the votes, subject only to the mandatory provisions of the Danish Companies Act and the articles of association. Resolutions concerning all amendments to the articles of association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder's ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose any or increase any obligations of the shareholders towards the company require unanimity.

Delaware. Under the Delaware General Corporation Law, a corporation's certificate of incorporation may be amended only if adopted and declared advisable by the board of directors and approved by a majority of the outstanding shares entitled to vote, and the bylaws may be amended with the approval of a majority of the outstanding shares entitled to vote and may, if so provided in the certificate of incorporation, also be amended by the board of directors.

Description of American Depositary Shares

Depositary

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

American Depositary Shares

The Bank of New York Mellon, as depositary, registers and delivers the ADSs. Each ADS represents one ordinary share (or a right to receive one ordinary share) deposited with The Bank of New York Mellon, London Branch, or any successor, as custodian for the depositary. Each ADS also represents any other securities, cash or other property which may be held by the depositary in respect of the depositary facility. The depositary's corporate trust office at which the ADSs are administered and its principal executive office is located at 240 Greenwich Street, New York, New York 10286.

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

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

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

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

Dividends and Other Distributions

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

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

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

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

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

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

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

U.S. securities laws may restrict transfers and cancellation of the ADSs representing ordinary shares purchased upon exercise of rights. For example, you may not be able to trade these ADSs freely in the United States. In this case, the depositary may deliver

restricted depositary shares that have the same terms as the ADSs described in this section except for changes needed to put the necessary restrictions in place.

Other Distributions. The depositary will send to you anything else we distribute to holders of deposited securities by any means it determines is equitable and practicable. If it cannot make the distribution proportionally among the owners, the depositary may adopt another equitable and practical method. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. In addition, the depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution.

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

Deposit, Withdrawal and Cancellation

How are ADSs issued?

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

How can ADS holders withdraw the deposited securities?

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

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

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

Voting Rights

How do you vote?

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

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

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

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your ordinary shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the

manner of carrying out voting instructions provided that any such failure is in good faith. This means that you may not be able to exercise your right to vote and there may be nothing you can do if your ordinary shares are not voted as you requested.

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

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

Fees and Expenses

What fees and expenses will you be responsible for paying?

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

Persons depositing or withdrawing ordinary shares or 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.

Payment of Taxes

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

Reclassifications, Recapitalizations and Mergers

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

Amendment and Termination

How may the deposit agreement be amended?

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

How may the deposit agreement be terminated?

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

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

Limitations on Obligations and Liability

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

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

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

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

Requirements for Depositary Actions

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

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

Your Right to Receive the Ordinary Shares Underlying Your ADSs

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

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

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

Pre-release of ADSs

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

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

Direct Registration System

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

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

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

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

Exhibit 4.16

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

Tech Transfer and Manufacturing Services Agreement

(the “Agreement”)

by and between

Lonza Ltd
Münchensteinerstrasse 38
CH-4002 Basel
Switzerland

- hereinafter “Lonza” -

and

Ascendis Pharma A/S
Company Reg. No. 29918791
Tuborg Boulevard 12
2900 Hellerup
Denmark

- hereinafter “Customer” -

Effective as of December 12, 2019 (the “Effective Date”)

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Recitals

WHEREAS, Customer is engaged in the development, research and commercialization of certain products and requires assistance in the development and manufacture of such product(s);

WHEREAS, Lonza and its Affiliates have expertise in the evaluation, development and manufacture of products;

WHEREAS, Customer wishes to engage Lonza for Services relating to the development and manufacture of the Product as described in this Agreement; and

WHEREAS, Lonza, or its Affiliate, is prepared to perform such Services for Customer on the terms and subject to the conditions set out herein.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the parties intending to be legally bound, agree as follows:

1 Definitions and Interpretation

"Affiliate"	means any company, partnership or other entity which directly or indirectly Controls, is Controlled by or is under common Control with the relevant Party. "Control" means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of the relevant Party.
"Agreement"	means this agreement incorporating all Appendices, as amended from time to time by written agreement of the Parties.
"Applicable Laws"	means all relevant [***] federal, state and local laws, statutes, rules, and regulations which are applicable to the performance of the Services (as defined below) and/or the Parties' respective obligations hereunder, including, without limitation, the applicable regulations and guidelines of any Governmental Authority and all applicable cGMP together with amendments thereto and shall be expanded to [***], at Ascendis' sole discretion and according to timelines subject to both Parties' mutual agreement reached in good faith; the Parties will cooperate in good faith in order to allow for an expansion to any further jurisdiction, including but not limited to [***] it being understood that any such expansion shall be subject to mutual agreement between the Parties.
"Approval"	means the first marketing approval by the FDA or EMA or other Regulatory Authority of the Drug Product manufactured by using the Product from the Facility for commercial supply.

“Background Intellectual Property”	means any Intellectual Property either (i) owned or controlled by a Party prior to the Effective Date or (ii) developed or acquired by a Party independently from the performance of the Services hereunder during the Term of this Agreement.
“Batch”	means the Product derived from a single run of the Manufacturing Process.
“Batch Price”	means the Price of each Batch.
“Batch Record”	means the executed document on the basis of the respective Master Batch Record containing the production record, or, as applicable, relevant portions thereof, pertaining to a given Batch, including the documentation on paper or in electronic form as EBR electronic batch record, created as and after each Batch is processed that, when complete and accurate, reflects and incorporates all aspects with respect to such Batch.
“Campaign”	means a series of no less than [***] ([***]) cGMP Batches manufactured consecutively.
“Cancellation Fee”	has the meaning given in Clause 6.7.
“[***]”	shall have the meaning set out in Clause 9.1.
“Capital Equipment”	means those certain pieces of equipment described in the Project Plan used to produce the Product that are purchased by Customer or for which Customer reimburses Lonza, including, without limitation, the related documentation regarding the design, validation, operation, calibration and maintenance of such equipment. For the avoidance of doubt, Capital Equipment does not include equipment already owned by Lonza as per the Effective Date, nor does it include replacement of such equipment [***].
“Certificate of Analysis” or “CoA”	means a document prepared by Lonza listing tests performed by Lonza or approved External Laboratories, on representative Batch sample(s), setting forth the Specifications, test methods used, actual results, date and signature of authorised personnel, and other technical information deemed necessary for its proper use, and, if External Laboratories have performed any such tests, the name and address of such External Laboratories.
“Certificate of Compliance” or “CoC”	means a document prepared by Lonza: (i) listing the manufacturing date, unique Batch number,

	and concentration of Product in such Batch, (ii) certifying that such Batch was manufactured in accordance with the Master Batch Record and cGMP, if applicable.
"cGMP"	means those laws and regulations applicable in [***], relating to the manufacture of medicinal products for human use, including, without limitation, current good manufacturing practices as specified in the ICH guidelines, including without limitation, ICH Q7A "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients", US Federal Food Drug and Cosmetic Act at 21CFR (Chapters 210, 211, 600 and 610, 820) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC. For the avoidance of doubt, Lonza's operational quality standards are defined in internal cGMP policy documents.
"cGMPBatches"	means any Batches which are required under the Project Plan to be manufactured in accordance with cGMP.
"Change"	means any change to the Services, pricing or Scope of Work incorporated into a written amendment to the Agreement in accordance with clause 17.2 or effected in accordance with the Quality Agreement.
"Commencement Date"	means the date of commencement of manufacturing activities for a Batch hereunder.
"Confidential Information"	means Customer Information and Lonza Information, as the context requires.
"Customer Information"	means all technical and other information that is proprietary to Customer and that is maintained in confidence by Customer and that is disclosed by Customer to Lonza or in the public domain relating to the Manufacturing Process and the Product, from time to time supplied by the Customer to Lonza, including any materials supplied by Customer to Lonza in accordance with the Project Plan.
"Customer Materials"	means any Raw Materials, components of Product, or other materials of any nature provided by Customer as agreed between the Parties, including, without limitation, any handling instructions, protocols, SOPs and other documentation necessary to maintain the properties of such Customer Materials for the performance of the Project Plan.

“Customer Release”	has the meaning given in Clause 7.1.
“[***] Date”	means the date Customer Release is given regarding a Batch or [***] days after Lonza Release, whichever comes first.
“Development Services”	means all Services other than Manufacturing Services.
“Drug Product”	means any drug product incorporating Product.
“EMA”	means the European Medicines Agency, or any successor agency thereto.
“Engineering Batches”	means a Batch that is intended to demonstrate the transfer of the Manufacturing Process to the Facility.
“External Laboratories”	means any Third Party instructed by Lonza, with Customer’s prior consent, which is to conduct laboratory services activities required to complete the Services which are not customarily offered by Lonza and performed on an independent and impartial basis.
“Facility”	means, for the manufacture of Product, [***], or, to the extent agreed between Customer and Lonza, for the manufacture of [***], [***], or such other Lonza facility as may be agreed upon by the Parties.
“FDA”	means the United States Food and Drug Administration, or any successor agency thereto.
Flex Batch”	has the meaning given in Clause 6.1.2(a).
“GDPR”	means the European Union General Data Privacy Regulation.
“Governmental Authority”	means any Regulatory Authority and any national, multi-national, regional, state or local regulatory agency, department, bureau, or other governmental entity in [***] or such other jurisdiction as the Parties may mutually agree upon in alignment with any expansion of the Applicable Law.
“International Trade Restrictions”	means all applicable [***] export control, trade, and financial sanctions laws, rules, and regulations.
“Intellectual Property”	means (i) inventions (whether or not patentable), patents, trade secrets, copyrights, trademarks, trade names and domain names, rights in designs, rights in computer software, database

	rights, rights in confidential information (including know-how) and any other intellectual property rights, in each case whether registered or unregistered, (ii) all applications (or rights to apply) for, and renewals or extensions of, any of the rights described in the foregoing clause (i) and (iii) all rights and applications that are similar or equivalent to the rights and application described in the foregoing clauses (i) and (ii), which exist now, or which come to exist in the future, in any part of the world.
“Lonza Information”	means all information that is proprietary to Lonza or any Affiliate of Lonza and that is maintained in confidence by Lonza or any Affiliate of Lonza and that is disclosed by Lonza or any Affiliate of Lonza to Customer under or in connection with this Agreement, including without limitation, any and all Lonza know-how and trade secrets.
“Lonza Operating Documents”	means the corporate standards, standard operating procedures, standard manufacturing procedures, Lonza-customized manufacturing procedures developed or outside the scope of this Agreement, electronic programs and files, raw material specifications, protocols, validation documentation, and supporting documentation used by Lonza, without limitation, [***], excluding any of the foregoing that are unique to the manufacture of Product.
“Lonza Release”	has the meaning given in Clause 7.1.
“Manufacturing Process”	means the production process provided by Customer to Lonza for the manufacture of Product, as such process may be improved or modified from time to time by agreement of the Parties in writing.
“Manufacturing Services”	means the services related to the manufacturing of Batches (including Engineering Batches and PPQ Batches), as well as the related pre-production activities and, to the extent agreed by the Parties in an amendment hereto, the manufacturing of related materials, such as any enzymes to be used for the manufacturing of the Product (including [***]); for the avoidance of any doubt, the manufacturing of any Engineering Batch or Process Validation Batch or commercial Batch is deemed Manufacturing Services.
“Master Batch Record”	means the formal set of unexecuted master production and control records and instructions for the manufacture of the Product or, to the extent requested by Customer, the [***] that

	details steps and elements of the Manufacturing Process, along with analytical methods, test methods and other procedures, directions and controls associated with the manufacture and testing of the Product.
“Modified Manufacturing Process”	means a Manufacturing Process that has been improved or modified by agreement of the Parties and incorporates any Lonza Information, Lonza Background Intellectual Property and/or New General Application Intellectual Property.
“New Customer Intellectual Property”	has the meaning given in Clause 10.2.
“New General Application Intellectual Property”	has the meaning given in Clause 10.3.
“Party”	means each of Lonza and Customer and, together, the “Parties”.
“Price”	means the price for the Services and Products as set out in Appendix A.
“Process Validation Batch or PPQ Batch”	means a Batch that is produced in compliance with cGMP with the intent to show reproducibility of the Manufacturing Process and is required to complete process validation studies.
“Product”	means the proprietary molecule identified by Customer as TransCon [***] human Growth Hormone (TC hGH) [***] to be manufactured using the Manufacturing Process by Lonza for Customer as specified in the Project Plan.
“Project Plan”	means the plan(s) describing the Services to be performed by Lonza under this Agreement, including any update and amendment of the Project Plan to which the Parties may agree from time to time. The initial Project Plan is attached hereto as Appendix A.
“Purchase Order”	shall have the meaning ascribed in Clause 6.2.
“Roadmap”	shall have the meaning ascribed in Clause 2.2.1.
“Quality Agreement”	means the quality agreement, attached or to be attached no later than before commencement of any cGMP manufacturing hereto as Appendix H, that delineates, defines, establishes, and documents manufacturing and testing activities and responsibilities of the Parties subject to cGMP requirements.

“Raw Materials”	means all ingredients, including [***] unless such [***] is manufactured by Lonza based on an amendment to this Agreement between the Parties, and [***] required to perform the Manufacturing Process or Services set forth in the bill of materials detailing the same (including any consumables or wearables).
“Raw Materials Handling Fee”	means the procurement and handling fee of a percentage, as stipulated in Clause 8.2, of the acquisition cost of Raw Materials other than Customer Materials by Lonza that is charged to the Customer in addition to the cost of such Raw Materials. For the avoidance of doubt: If Lonza manufactures [***] for Customer, such shall be priced according to an agreed batch fee and shall not be subject to the Raw Materials Handling Fee, except for the Raw Materials used in such enzyme production.
“Recall”	has the meaning given in Clause 12.4
“Regulatory Authority”	means the [***] and any other similar regulatory authorities as may be agreed upon in writing by the Parties that are responsible for administering and/or granting approvals for the performance of Services under this Agreement or for issuing regulations pertaining to the manufacture and/or use of Product in [***] or in such other countries as the Parties may mutually agree upon.
“[***]”	means [***], as specified in the Master Batch Record.
“[***] Handling Fee”	means the procurement and handling fee of a percentage, as stipulated in Clause 8.2, of the acquisition cost of [***] by Lonza that is charged to the Customer in addition to the cost of such [***].
“Services”	means all or any part of the services to be performed by Lonza or its Affiliates under this Agreement (including, without limitation, process and analytical method transfer, process development, process optimization, validation, BLA related activities, clinical and commercial Manufacturing Services, as well as quality control and quality assurance activities including without limitation analytical activities), particulars of which are set out in a Project Plan.
“SOP”	means a standard operating procedure.
“Specifications”	means the specifications of the Product as specified in Appendix B, which may be amended from time to time by mutual consent of both Parties in accordance with this Agreement.

"Subcontractors"	means any Third Party, which is not an External Laboratory, instructed by Lonza, with Customer's prior consent, which is to conduct activities required to complete the Services.
"[***]"	means [***].
"Term"	has the meaning given in Clause 15.1.
"Third Party"	means any party other than Customer, Lonza and their respective Affiliates.

In this Agreement references to the Parties are to the Parties to this Agreement, headings are used for convenience only and do not affect its interpretation, references to a statutory provision include references to the statutory provision as modified or re-enacted or both from time to time and to any subordinate legislation made under the statutory provision, references to the singular include the plural and vice versa, and references to the word "including" are to be construed without limitation.

2 Performance of Services

2.1 Performance of Services. Subject to Clause 2.3, Lonza shall itself and/or through its Affiliates, diligently carry out the Services as provided in the Project Plan and [***] perform the Services without defect and according to the estimated timelines as set forth in the Project Plan. Lonza shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with current industry standards and the terms of this Agreement. Lonza may subject to Customer's prior written approval subcontract or delegate parts of its performance of the Services to Subcontractors or External Laboratories, it being understood that Lonza will clarify at the time of seeking approval, whether the engagement is for a Subcontractor or External Laboratory; provided, that any Subcontractors shall be subject to the same obligations and other provisions contained in this Agreement or any applicable Project Plan. [***].

2.2 Technology Transfer to Lonza.

2.2.1 The Parties expressly agree that they shall work together to transfer the Manufacturing Process to the Facility, including implementing the technology transfer plan set forth in the Project Plan. Customer shall [***] support such technology transfer as reasonably requested by Lonza. A roadmap has been compiled and agreed by the Parties towards [***] (the "Roadmap"). Upon alignment between Customer and Lonza on the Roadmap, activities for the technology transfer will be started.

2.2.2 Based on the information provided by Customer and including process changes developed by Lonza pursuant to any applicable Project Plan, Customer shall inform Lonza of any specific requirements Customer may have, including, without limitation, any information or procedures Customer wishes to have incorporated therein. [***].

2.3 Engineering Batches. Lonza shall manufacture Engineering Batches in accordance with the Project Plan. Customer shall have the right to make whatever further use of

the non-cGMP Engineering Batches as it shall determine, provided that Customer pays for such Batches, such use is not for human use and does not violate any Applicable Laws. Lonza makes no warranty that Engineering Batches will meet cGMP or the Specifications. [***] Regardless of whether any Engineering Batch meets cGMP or the Specifications, Customer shall pay to Lonza the Price for such Engineering Batch plus the Raw Materials Handling Fee associated with such Engineering Batches.

2.4 cGMP Batches. Lonza will, in accordance with the terms of this Agreement and Quality Agreement, manufacture at the Facility and release to Customer, cGMP Batches that comply with the Manufacturing Process, cGMP and the Specifications, together with a Certificate of Analysis; [***]. Prior to commencement of cGMP manufacturing, Lonza shall review the process assumptions. In the event that there is a material difference in the process assumptions as compared with the process results demonstrated during the manufacture of Engineering Batches, [***].

2.5 Process Validation Batches. Lonza shall manufacture and deliver Process Validation Batches as mutually agreed by Parties sufficient to document the operability and reproducibility of the Manufacturing Process and permit the Parties to complete and file the necessary regulatory documents.

2.5.1 Prior to commencement of Process Validation Batches, Lonza and Customer shall agree a process validation plan identifying the validation requirements of the Manufacturing Process. All process validation activities are excluded from the Price of Process Validation Batches and shall be approved separately by the Customer in advance and shall be paid for by the Customer at the Price set out in the applicable Project Plan.

2.5.2 Any regulatory support activities (including pre-Approval inspection) required and agreed to by Customer to support the Approval of the Product from the Facility shall be performed and supported by Lonza as reasonably requested by Customer or required by a Governmental Authority[***]. All such regulatory support activities are excluded from the Price of Process Validation Batches, and shall be approved by the Customer in advance, and shall be paid for by the Customer at the Price set out in the applicable Project Plan (and/or amendments to this Agreement or scope change documents).

2.6 Supply of Customer Information and Customer Materials. Customer shall supply to Lonza all Customer Information and Customer Materials and other information or materials that may be reasonably required by Lonza to perform the Services. [***]. Customer Materials shall remain the property of the Customer and shall until processing be clearly marked as such [***].

2.7 Raw Materials. Lonza shall procure all required Raw Materials as well as consumables other than those Raw Materials that are Customer Materials. At Customer's sole discretion and upon advance payment by Customer, Lonza shall purchase and hold a minimum of [***] ([***]) (or such other number the Parties may mutually agree upon at a later stage) extra Batch's requirements of Raw Materials to serve as safety stock. Customer shall be responsible for payment for all consumables and Raw Materials ordered or irrevocably committed to be procured by Lonza hereunder. The Parties recognize and agree that any Raw Materials or [***] fully paid up in advance by the Customer is the property of the Customer. Upon cancellation of any Batch or termination of the Agreement, all unused Raw Materials which cannot be used by Lonza for the manufacture of other products for other customers shall be paid for by Customer within [***] ([***]) days of invoice and at Customer's option and cost will either be (a) held by Lonza for future use for the production of Product for up to [***] of the last Process Validation Batch and (b) [***] ([***]) months thereafter, (b) delivered to Customer, or (c) disposed of [***].

3 Project Management / Steering Committee

3.1 Project Plans. With respect to a new project to be governed by this Agreement, a new Project Plan shall be added by agreement in writing signed by the Parties and appended to Appendix A. Each Project Plan shall include a description of the Services to be provided, the Product to be manufactured, Specifications, a schedule for completion of the Project Plan, pricing details, and such other information as is necessary for relevant Services. In the event of a conflict between the terms of a Project Plan and this Agreement, the terms of this Agreement will govern.

3.2 Project Management. With respect to each Project Plan, each party will appoint a project manager who will be the party responsible for overseeing the Project Plan.

3.3 Steering Committee. Each Party shall name a mutually agreed upon equal number of representatives for the Steering Committee, which shall meet [***] per calendar year, or as otherwise mutually agreed by the Parties. In the event that a Steering Committee dispute cannot be resolved, such dispute shall be escalated to a senior executive of each of Customer and Lonza.

The primary function of the Steering Committee is to ensure the ongoing communication between the Parties and discuss and resolve any issues arising under this Agreement. In addition to the primary function described above, the Steering Committee shall also take on the following responsibilities:

3.3.1 discuss and seek resolution of issues around management of the Services;

3.3.2 agree and monitor deadlines and milestones for the Services; and

3.3.3 discuss and recommend any changes to the Services (although such changes will not take effect until they have been incorporated into a written amendment to the Project Plan which has been signed by the Parties).

3.4 Person in Plant. Customer shall be permitted to have, at no additional cost, [***] ([***]) [***] at the Facility as reasonably requested by Customer, at any time during the Manufacturing Process and related analytical services for the purpose of observing, reporting on, and consulting as to the performance of the Services. Such employee shall be subject to and agree to abide by confidentiality obligations to Third Parties and Lonza's customary practices and operating procedures regarding persons in plant, and such employee agrees to comply with all instructions of Lonza's employees at the Facility. Furthermore, Lonza shall use commercially reasonable endeavours that Customer is allowed similar access to key Subcontractors and External Laboratories.

4 Quality

4.1 Responsibility for quality assurance and quality control of Product shall be allocated between Customer and Lonza as set forth in the Quality Agreement and in Lonza standard operating procedures. If there is a conflict between the terms and conditions of this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall prevail except in quality related matters, where the Quality Agreement shall prevail. If the Quality Agreement is not in place at the Effective Date, Lonza and Customer commit to enter into the Quality Agreement in a timely manner, but in no event later than [***].

4.2 Provisions regarding inspections by Regulatory Authorities and audits shall be set out in the Quality Agreement.

5 Insurance

5.1 Each Party shall, during the Term and for [***] ([***]) years after delivery of the last Product manufactured or Services provided under this Agreement, obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance including, but not limited to product liability coverage in the amount of at least [***] per claim. Each Party shall provide the respective other Party with a certificate of such insurance upon reasonable request.

6 Forecasting, Ordering and Cancellation

6.1 Forecasting and Ordering.

6.1.1 No later than the [***] ([***]) day of each [***] following the Effective Date of Agreement [***], Customer shall supply Lonza with a written forecast showing Customer's good faith estimated requirements for Batches to be delivered for the following [***] ([***]) [***] period, starting with the [***] (the "Forecast"). The Forecast shall show a good faith estimate of the demand on a semi-annual basis for the non-binding period and the [***] demand for the Binding Forecast (as defined in Clause 6.1.2(a) below). The Parties acknowledge and agree that as of the Effective Date Customer has provided Lonza with its initial forecast attached as Appendix C of Customer's good faith estimated requirements for Batches to be manufactured in the Facility and such forecast shall be deemed a Forecast.

6.1.2 No later than [***] ([***]) days following Lonza's receipt of a Forecast, Lonza shall provide written notice to Customer of whether it has (as of the date of receipt of the Forecast) capacity available to manufacture the number of Batches forecasted therein and shall provide Customer with an estimated production schedule showing the estimated [***] Date of each Batch. If upon receipt of a Forecast Lonza determines that it will not have sufficient capacity to meet the forecasted requirements, Lonza will promptly notify Customer and the parties will work together in good faith to determine how to meet Customer's requirements.

(a) The first [***] ([***]) [***] of any Forecast shall be binding ("Binding Forecast"). No Forecast shall amend any previous Binding Forecast. [***];

6.2 Purchase Orders.

6.2.1 Development Services. Customer shall place work orders for the Development Services it wishes to order at least [***] ([***]) [***] or earlier as reasonably required prior to the Commencement Date for such Development Services, taking into consideration Lonza's most recent Project Plan, provided that at all times the Parties shall use reasonable endeavours to agree upon the time at which such Development Services will be performed.

6.2.2 Manufacturing Services. Customer shall place binding purchase orders ("Purchase Orders") for manufacturing Campaigns in the Facility consistent to, and within [***] ([***]) days from, the most recent response by Lonza to the Forecast as per Clause 6.1.2 at least [***] ([***]) [***] prior to the estimated [***] Date for the first Batch of such Campaign in accordance with Lonza's most recent response to the respective Forecast.

6.3 Order Confirmation. Lonza shall confirm each Purchase Order within [***] ([***]) [***] days of receipt from Customer of the relevant Purchase Order. For Batches manufactured for commercial use (excluding, for clarity, any Clinical Batches, Engineering Batches and Validation Batches) the Purchase Order shall set out the latest [***] Date(s) and quantity of Product to be delivered. Upon confirmation, each Purchase Order will be regarded by the Parties as a binding commitment by Lonza to manufacture and to deliver to Customer the relevant number of Batches or to provide the Development Services according to the requirements set out in such Purchase Order. Subject to Clause 6.4 any [***] Date set forth in Lonza's written confirmation of a purchase order shall be the ultimate [***] Date of the first Batch of the Campaign, allowing delivery up to [***] [***] earlier. All ordered Batches shall be scheduled in a single Campaign in each [***], excluding the first [***] ([***]) [***] after the Lonza Release of the last Process Validation Batch (forecast for the [***] of the last batches of commercial campaigns may be up to [***] ([***]) [***] apart during this period), unless otherwise agreed by Lonza. Any additional or inconsistent terms or conditions of any Customer purchase order, acknowledgement or similar standardized form given or received pursuant to this Agreement shall have no effect and such terms and conditions are hereby rejected.

6.4 Rescheduling. Lonza shall have the right to reschedule a [***] Date of any Batch or Campaign upon reasonable prior written notice to Customer, provided that (i) the rescheduled [***] Date is no later than [***] ([***]) days from the [***] Date originally estimated at the time of Lonza's acceptance of the binding purchase order (the "Original [***] Date"), and (ii) that the [***] Date of the first Batch of the Campaign is not to occur earlier than [***] ([***]) days before the Original [***] Date. If the Customer requests to change the [***] Date, Lonza will make all reasonable attempts to accommodate the request; provided, however, in the event that this change would impact other projects scheduled for occupancy in the designated suite or suites, [***]. Any such change requested by Customer [***]. Any delay requested by Customer of more than [***] ([***]) days shall be considered a cancellation pursuant to Clause 6.76.

6.5 Minimum Quantity and Volume Commitments. Provided Customer has obtained Approval for the Drug Product manufactured by using the Product from the Facility in the US or EU, Customer undertakes to purchase from Lonza and Lonza undertakes to be able to supply a minimum of at least [***] ([***]) Batches of Product manufactured [***] in one Campaign per calendar year commencing in [***] (the **"Minimum Quantity**"). In addition, [***] Customer undertakes to purchase from Lonza at least [***] percent ([***]%) for the first [***] ([***]) years [***] and thereafter [***] percent ([***]%) of Customer's annual requirement of Product beyond [***] kg and up to the lower of [***] ([***]) Batches or [***] kg starting with the [***] (the "**Volume Commitment**").

6.6 Failure to comply with Minimum Quantity and Volume Commitments.

6.6.1 If Customer fails to purchase the Minimum Quantity, Customer shall pay the Price per Batch for the number of Batches below the minimum within [***] ([***]) [***].

6.6.2 Within [***] ([***]) days of the end of each calendar year, [***]. In the event Lonza believes, [***], that the Customer falls short of the Volume Commitment, [***].

6.6.3 Lonza commits to deliver to the Forecast, up to a maximum of [***] ([***]) Batches or of [***] kg per year, whichever is lower, provided that it is within the

binding part of the Forecast. Such capacity may be reserved for the Customer for years [***] up to [***] of the Forecast. However, if another customer wishes to order such capacity in parts or full, [***]

6.7 Cancellation of a Binding Purchase Order. Customer may cancel a binding Purchase Order upon written notice to Lonza, subject to the payment of a cancellation fee as calculated below (the "Cancellation Fee"):

6.7.1 In the event that Customer provides written notice of cancellation to Lonza less than or equal to [***] ([***]) months prior to the [***] Date of one or more Batches [***], then [***] percent ([***]%) of the Batch Price of each such Batch cancelled is payable, provided that [***];

6.7.2 In the event that Customer provides written notice of cancellation to Lonza less than or equal to [***] ([***]) months prior to the [***] Date of [***], then [***] percent ([***]%) the Batch Price of each such Batch cancelled is payable, provided that [***]; and

6.7.3 In the event that Customer provides written notice of cancellation to Lonza of more than [***] ([***]) months prior to the [***] Date of one or more Batches, then no cancellation fee is due.

6.8 Payment of Cancellation Fee. Any Cancellation Fee shall be payable latest by the original Commencement Date associated with the cancelled Batch of Development or Manufacturing Service. Any Cancellation Fee shall include all documented costs associated with the cancelled Batch, including any Raw Materials, [***], Raw Materials Handling Fee and [***] Handling Fee.

6.9 Replacement Project. Notwithstanding the foregoing, Lonza will use commercially reasonable efforts to secure a new or additional project (but excluding any project or production then under contract with Lonza with a [***] Date that is [***] ([***]) months or less after the notification date of the applicable cancellation or rescheduling by Customer) for the development or manufacturing space, and for dates and duration that would have been occupied by Customer (a "New Project"). If Lonza is able to secure a New Project with Customer or another Lonza customer (the "Replacement Services"), then, in such case, the Cancellation Fee for Development Services or Manufacturing Services cancelled that is replaced by a New Project shall be reduced or credited to Customer (if applicable) towards the New Project by an amount equal to [***] percent ([***]%) of the respective Cancellation Fee pro-rated to the Facility occupancy (on a per diem basis) with such Replacement Services. .

6.10 Enzymes. Unless otherwise specified in an amendment to this Agreement, the provisions of this Clause 6 shall also apply to the forecasting, ordering and cancelling of any enzyme, including [***], the Parties may mutually agree to be manufactured by Lonza.

7 Delivery and Acceptance

7.1 Acceptance/Rejection of Product.

7.1.1 Lonza shall perform its own release of Batches (the "Lonza Release"). Promptly following the Lonza Release of a Batch Lonza shall deliver to Customer the Certificate of Analysis, any other documentation as specified in the Quality Agreement, and such other documentation as is reasonably required and

notified in advance by Customer to meet all applicable regulatory requirements of the Governmental Authorities. Customer shall review such Documentation and Lonza shall promptly answer all questions from Customer and perform additional investigations as requested. Customer shall notify Lonza in writing of the final release ("Customer Release") or rejection of the batch without undue delay.

7.1.2 Promptly following the [***] Date of Batches, Customer shall inspect such Batches and shall have the right to test such Batches to determine compliance with the Specifications. Customer shall notify Lonza in writing of any rejection of a Batch based on any claim that it fails to meet Specifications or comply with cGMP upon agreed procedures as agreed in the Quality Agreement, but no later than within [***] ([***]) days of [***] Date, after which time all unrejected Batches shall be deemed accepted, except for concealed or latent defects. In case of concealed or latent defects discovered later, such notification to be given in writing promptly upon discovery of such defects but, for concealed or latent defects, no later than [***] after Delivery of the Product.

7.1.3 In the event that Lonza believes that a Batch has been incorrectly rejected, Lonza may require that Customer provide to it Batch samples for testing. Lonza may retain and test the samples of such Batch. In the event of a discrepancy between Customer's and Lonza's test results such that Lonza's test results fall within relevant Specifications, or there exists a dispute between the Parties over the extent to which such failure is attributable to a given Party, the Parties shall cause an independent laboratory promptly to review records, test data and perform comparative tests and analyses on samples of the Product that allegedly fails to conform to Specifications. Such independent laboratory shall be mutually agreed upon by the Parties. If the Parties are unable to agree on an independent laboratory, [***] shall appoint such laboratory. The independent laboratory's results shall be in writing and shall be final and binding [***]. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules.

7.1.4 Lonza shall reprocess free of charge any Batch or, if reprocessing is not possible, replace any Batch that failed to conform with the Specifications or was not manufactured in compliance with cGMP (a "Failed Batch"), in the event that it is determined (by the Parties or the independent laboratory) that such failure was [***] ("Lonza Responsibility"); in the event of [***]. Provided a Lonza Responsibility is confirmed, such reprocessing or replacement shall be made as promptly as practicable, in light of available manufacturing capacity and Raw Materials, and in any case as soon as reasonably possible. [***] Customer acknowledges and agrees that its sole remedy with respect to a Failed Batch that is a Lonza Responsibility is as set forth in this Clause 7.1.4., and in furtherance thereof, Customer hereby waives all other remedies at law or in equity regarding the foregoing claims.

7.2 Delivery. All Product shall be delivered [***] (as defined by Incoterms® 2010) the Facility. Delivery is considered to have taken place when "Customer Release" has been notified to Lonza or [***] days after the Release by Lonza, whichever comes first. With respect to any Customer Materials, title and risk of loss shall remain with the Customer and shall not transfer to Lonza, except as set forth in Clause 7.1.4 in case of a Failed Batch as a direct result of Lonza Responsibility. With respect to Product and Raw Materials other than Customer Materials, title and risk of loss shall transfer to Customer upon Delivery.

7.3 Storage. Customer shall arrange for shipment and take delivery of such Batch from the Facility, at Customer's expense, within [***] ([***]) days after Customer Release or pay applicable storage costs. Lonza shall provide storage on a bill and hold basis for such Batch(es) at no charge for up to [***] ([***]) days; provided that any additional storage beyond [***] ([***]) days will be charged on a monthly basis to Customer and may be subject to a separate agreement. In addition to Clause 8.2, Customer shall be responsible for all value added tax (VAT) and any other applicable taxes, levies, import, duties and fees of whatever nature imposed as a result of any storage. Notwithstanding anything to the contrary contained in this Agreement, Lonza shall not be required to store any Batch for more than [***] ([***]) calendar days after Customer Release, [***], subject to availability and the applicable storage costs to be paid by Customer. Within [***] ([***]) days following a written request from Lonza, Customer shall provide Lonza with a letter [***] confirming the [***] of each stored Batch.

8 Price and Payment

8.1 Pricing. Pricing for the Services provided by Lonza [***], any Scope Change or Work Order, and based on the assumptions and information set out in, the applicable Project Plan. In the event of changes to the Services based on additional operational requirements or Customer's request, Lonza and Customer shall discuss in good faith and agree on any additional costs. [***] Any additional costs arising from [***] (including, without limitation Capital Equipment required for its implementation, methods of analysis, set-up cost or adjustments to Batch pricing) shall be fully assumed by the Customer.

8.2 Handling Fees. The Raw Materials Handling Fee shall be [***] percent ([***]%) and the [***] Handling Fee shall be [***] percent ([***]%) [***].

8.3 Taxes. Unless otherwise indicated in writing by Lonza, all Prices and charges are exclusive of value added tax (VAT) and of any other applicable taxes, levies, import, duties and fees of whatever nature imposed by or under the authority of any government or public authority and all such charges applicable to the Services shall be paid by Customer. When sending payment to Lonza, the Customer shall quote the relevant invoice number in its remittance advice.

8.4 Invoicing. Lonza shall issue invoices to Customer as follows:

8.4.1 All Development Services and Manufacturing Services shall be invoiced as follows:

- [***] percent ([***]%) of the Price for all Batches or Services upon the [***] Date of such Batch or Service; and
- [***] percent ([***]%) upon [***] Date of each Batch or completion of applicable Services.

8.4.2 Charges for Raw Materials and the Raw Materials Handling Fee for each Batch shall be invoiced as follows:

- [***]

8.4.3 Purchase cost for [***] shall be invoiced by Lonza at [***]% of the [***] cost and [***] Handling Fee upon the date the applicable Purchase Order is accepted by Lonza, but no earlier than Lonza issuing the purchase order to its [***] supplier.

All invoices are strictly net and payment for amounts not subject to a bona fide dispute must be made within [***] ([***]) days of Customer's receipt of the applicable invoice, without deduction, deferment, set-off, lien or counterclaim.

8.5 Payment Default. If in default of payment of any undisputed invoice on the due date, interest shall accrue on any amount overdue at the lesser of (i) rate of [***] or (ii) the maximum rate allowable by law governing this Agreement, interest to accrue on a day to day basis until full payment; and Lonza shall, at its sole discretion, and without prejudice to any other of its accrued rights, be entitled to suspend the provision of the Services and or delivery of Product until all overdue amounts have been paid in full including interest for late payments.

8.6 Price adjustments.

8.6.1 Not more than once per calendar year, starting [***], Lonza may, by notification sent no later than [***] of the prior year, adjust the Price in accordance with the [***] (or any successor index) increase for the previous calendar year (there is no decrease if the [***] goes down provided, however, that in the event of a decrease of such index an adjustment shall only be possible after such index has exceeded the index position on which the last adjustment was based). The new Price reflecting such Batch Price adjustment shall be effective for any Batch for which the Commencement Date is on or after the date of Lonza's notice to Customer of the Price adjustment.

8.6.2 In addition to the above, the Price may be changed by Lonza, upon reasonable prior written notice to Customer (providing reasonable detail in support thereof), to reflect (i) [***], or for a [***], and (ii) [***].

8.6.3 The Parties will work together to jointly develop a continuous improvement plan in order to achieve cost reductions for validated processes. Customer shall benefit fully from improvements initiated and developed by Customer and transferred to Lonza. In respect of any Modified Manufacturing Process resulting from jointly initiated and/or performed improvements Customer shall benefit by [***] percent ([***]%) of the improvement so derived. Lonza shall retain all benefits of any Modified Manufacturing Process to extent Customer did neither initiate nor participate in the improvement or modification.

9 Capital Equipment

9.1 Any Capital Equipment required for the performance of the Services shall be acquired on terms to be agreed by the Parties prior to the Commencement Date of the relevant Services it being understood that irrespective of such terms the capital equipment will be the sole property of Lonza. Any Capex funded by Lonza for such Capital Equipment, upon Customer's request and pre-approval of the cost thereof in writing, shall be reimbursed by Customer [***].

9.2 [***].

9.3 Any Capital Equipment required to [***] will be funded by Customer, but shall remain subject to [***].

10 Intellectual Property

10.1 Background Intellectual Property

10.1.1 Except as expressly otherwise provided herein, neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Background Intellectual Property of the other Party, including any improvements made thereto during the performance of the Services under this Agreement.

10.2 New Intellectual Property Ownership

10.2.1 [***] Ownership. Subject to Clause 10.3, [***] develop, conceive, invent, first reduce to practice or make, solely or jointly with [***], in the course of the [***], to the extent that is both:

(i) a derivative of or improvement to [***], and

(ii) [***]. For avoidance of doubt, [***] shall include any [***], but excluding any [***]

10.2.2 [***] Ownership. Notwithstanding Clause 10.2.1, [***], develop, conceive, invent, or first reduce to practice or make solely or jointly with [***], in the course of [***] that is generally applicable to the [***]. For avoidance of doubt, [***] shall include any [***]

10.2.3 Assignment of New Intellectual Property. [***] hereby assigns to [***] all of its right, title and interest in any [***]. To the extent that [***] has or obtains any rights, title or interest in [***] hereby assigns to [***] all of its right, title and interest in any [***].

10.3 License Grants.

10.3.1 Subject to the terms and conditions set forth herein (including the payment of the Price as required above), Lonza hereby grants to Customer a [***]

10.3.2 Customer hereby grants Lonza and its Affiliates, sub-contractors and the External Laboratories the [***] solely for the purpose of fulfilling its obligations under this Agreement.

10.3.3 Unless the Parties expressly, mutually agree to the contrary herein in writing, including without limitation by express reference to a given OtherAgreement (defined below), nothing in this Agreement (or any Project Plan entered into pursuant to this Agreement) shall supersede, amend or otherwise modify any terms or conditions or other provisions of any other agreement between the Parties that is entered into prior to or contemporaneously with the execution of this Agreement, including, without limitation, any agreement related to any [***], or any services performed by Lonza or any Affiliate of Lonza for Customer, or any consumables or other products supplied by Lonza or any Affiliate to Customer (collectively, an “Other Agreement”).

10.4 Technology Transfer to Customer or Third Party Manufacturer.

10.4.1 Upon the written notification by Customer to Lonza and subject to the terms and conditions of this Clause 10.4 [***], and [***], and [***], Customer will be permitted to transfer the Manufacturing Process to itself and/or any Third Party manufacturer for the manufacture of the Product or, to the extent agreed by the Parties, the [***] (but no other product) at a particular site. For the avoidance of any doubt [***].

Customer shall provide written notice to Lonza at least [***] ([***]) days in advance that it wishes to exercise its rights under this Clause 10.4 (the "Technology Transfer Notice"). The Technology Transfer Notice shall provide reasonable details to Lonza about [***]. In the case of a proposed transfer of the Manufacturing Process to a Third Party, Customer shall indicate details about [***]

10.4.2 If the Technology Transfer Notice is [***], Lonza's consent to such requested transfer shall not be unreasonably withheld or delayed. If the Technology Transfer Notice is [***], (i) Customer must seek and obtain from Lonza approval for such transfer prior to any such transfer [***], and (ii) the Parties shall, agree on terms governing such technology transfer, including [***]

10.4.3 Lonza shall not be obliged to transfer any Modified Manufacturing Process to any Third Party (a) [***], and/or (b) [***].

For any transfer under this Clause 10.4, Lonza shall provide reasonably necessary documents (including the Product-specific Batch Records, deviations, root cause analyses, and release reports, technology transfer guidance and summary report and process protocols) to complete such technology transfer and [***]

10.5 Prosecution of Patents.

10.5.1 Subject to the following subsection, Customer will have the sole right and discretion to file (or not file), prosecute and maintain patent applications and patents claiming the New Customer Intellectual Property, at Customer's expense. Lonza will cooperate with Customer, at Customer's expense, to file, prosecute, maintain, defend, and enforce patent applications and patents claiming any New Customer Intellectual Property.

10.5.2 Unless the Parties agree otherwise, at least [***] ([***]) days prior to [***]. Within [***] ([***]) days of receipt of [***]. As determined by Lonza, [***]

10.5.3 Lonza will have the sole right and discretion to file (or not file), prosecute and maintain patent applications and patents claiming the New General Application Intellectual Property, at Lonza's expense. Customer will cooperate with Lonza[***] to file, prosecute, maintain, defend, and enforce patent applications and patents claiming any New General Application Intellectual Property.

11 Warranties

11.1 Lonza warrants that:

11.1.1 the Services shall be performed in accordance with all Applicable Laws;

11.1.2 except with respect to any development services and Engineering Batches, the manufacture of Product shall be performed in accordance with cGMP and will meet the Specifications at the date of Delivery;

11.1.3 it or its Affiliates hold all necessary permits, approvals, consents and licenses to enable it to perform the Services at the Facility, except to the extent that failure to maintain such licenses, permits and approvals do not have a material adverse impact on the ability to manufacture the Product in the Facility, or on the Services provided under this Agreement;

11.1.4 to its knowledge, the conduct and the provision of the Services shall not infringe, misappropriate or violate (as the case may be) any proprietary or Intellectual Property rights of any Third Party;

11.1.5 it shall promptly notify Customer in writing if it receives or is notified of a formal written claim from a Third Party that Lonza Information, Lonza Background Intellectual Property or New General Application Intellectual Property, as it relates to the Services under this Agreement, or that the use by Customer thereof, to the extent permitted under this Agreement, infringes, misappropriates or violates (as the case may be) any proprietary or Intellectual Property rights of any Third Party; and

11.1.6 it has the necessary corporate authorizations to enter into and perform this Agreement.

11.2 Customer warrants that:

11.2.1 it has to the best of its knowledge as of the Effective Date all the rights necessary to permit Lonza to perform the Services without infringing the Intellectual Property rights of any Third Party and the performance of the Services shall to the best of Customer's knowledge as of the Effective Date not infringe, misappropriate or violate (as the case may be) any proprietary or Intellectual Property rights of any Third Party;

11.2.2 all Customer Materials shall be provided with a certificate of analysis or other relevant documentation demonstrating that such Customer Materials meet the following Lonza acceptance criteria: (i) [***], (ii) [***], (iii) [***], (iv) [***], and (v) [***]. In addition, [***], and will update, clarify, correct, supplement and amend such information as necessary;

11.2.3 it will promptly notify Lonza in writing if it receives or is notified of a formal written claim from a Third Party that Customer Information and Customer Intellectual Property or that the use by Lonza thereof for the provision of the Services infringes, misappropriates or violates (as the case may be) any proprietary or Intellectual Property or other rights of any Third Party;

11.2.4 in connection with its receipt and usage of the Services and Products, Customer shall [***]. Customer shall [***]. Customer confirms that [***]; and

11.2.5 it has the necessary corporate authorizations to enter into this Agreement.

11.3 DISCLAIMER: THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, AND ALL OTHER WARRANTIES, BOTH EXPRESS AND IMPLIED, ARE EXPRESSLY DISCLAIMED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

12 Indemnification and Liability

12.1 Indemnification by Lonza. Lonza shall indemnify the Customer, its Affiliates, and their respective officers, employees and agents ("Customer Indemnitees") for any loss, damage, costs and expenses (including reasonable attorney fees) that Customer Indemnitees may suffer as a result of any Third Party claim arising directly out of (i) [***] or (ii) [***]

12.2 Indemnification by Customer. Customer shall indemnify Lonza, its Affiliates, and their respective officers, employees and agents ("Lonza Indemnitees") from and against any loss, damage, costs and expenses (including reasonable attorney fees) that Lonza Indemnitees may suffer as a result of any Third Party claim arising directly out of (i) [***]; or (ii) [***]

12.3 Indemnification Procedure. If the Party to be indemnified intends to claim indemnification under this Clause 12, it shall promptly notify the indemnifying Party in writing of such claim. The indemnitor shall have the right to control the defense and settlement thereof; provided, however, that any indemnitee shall have the right to retain its own counsel at its own expense. The indemnitee, its employees and agents, shall reasonably cooperate with the indemnitor in the investigation of any liability covered by this Clause 12. The failure to deliver prompt written notice to the indemnitor of any claim, to the extent prejudicial to its ability to defend such claim, shall relieve the indemnitor of any obligation to the indemnitee under this Clause 12.

12.4 Recall.

12.4.1 If the Customer is required by a Regulatory Authority or voluntarily chooses to initiate a recall ("Recall") or withdrawal of any Drug Product, the Customer shall notify Lonza.

12.4.2 Lonza shall provide all reasonably requested assistance and information to Customers and cooperate with the Customer to implement the Recall in accordance with the protocols and procedures contained in the Quality Agreement.

12.4.3 [***]

12.4.4 [***]

12.5 DISCLAIMER OF CONSEQUENTIAL DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, LOST PROFITS OR LOST REVENUES ARISING FROM OR RELATED TO THIS AGREEMENT, EXCEPT TO THE EXTENT RESULTING FROM FRAUD, GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT.

12.6 LIMITATION OF LIABILITY. LONZA'S LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED, IN THE AGGREGATE, [***] TOTAL AMOUNTS PAID BY CUSTOMER TO LONZA [***] IN THE [***] PERIOD PRECEDING THE FIRST CLAIM FOR DAMAGES, EXCEPT TO THE EXTENT RESULTING FROM [***]

13 Confidentiality

13.1 A Party receiving Confidential Information (the "Receiving Party") agrees to strictly keep secret any and all Confidential Information received during the Term from or on behalf of the other Party (the "Disclosing Party") using at least the same level of measures as it uses to protect its own Confidential Information, but in any case at least commercially reasonable and customary efforts. Confidential Information shall include information disclosed in any form including but not limited to in writing, orally, graphically or in electronic or other form to the Receiving Party, observed by the

Receiving Party or its employees, agents, consultants, or representatives, or otherwise learned by the Receiving Party under this Agreement, which the Receiving Party knows or reasonably should know is confidential or proprietary.

13.2 Notwithstanding the foregoing, Receiving Party may disclose to any courts and/or other Governmental Authorities Confidential Information which is or will be required pursuant to applicable governmental or administrative or public law, rule, regulation or order. In such case the Party that received the Confidential Information will, to the extent legally permitted, inform the other Party promptly in writing and cooperate with the Disclosing Party in seeking to minimize the extent of Confidential Information which is required to be disclosed to the courts and/or authorities.

13.3 The obligation to maintain confidentiality under this Agreement does not apply to Confidential Information, which:

13.3.1 at the time of disclosure was publicly available; or

13.3.2 is or becomes publicly available other than as a result of a breach of this Agreement by the Receiving Party; or

13.3.3 as the Receiving Party can establish by competent proof, was rightfully in its possession at the time of disclosure by the Disclosing Party and had not been received from or on behalf of Disclosing Party; or

13.3.4 is supplied to a Party by a Third Party which was not in breach of an obligation of confidentiality to Disclosing Party or any other party; or

13.3.5 is developed by or on behalf of the Receiving Party independently from and without use of the Confidential Information, as evidenced by Receiving Party's contemporaneous written records.

13.4 The Receiving Party will use Confidential Information only for the purposes of this Agreement and will not make any use of the Confidential Information for its own separate benefit or the benefit of any Third Party including, without limitation, with respect to research or product development or any reverse engineering or similar testing. The Receiving Party agrees to return or destroy promptly (and certify such destruction) on Disclosing Party's request all written or tangible Confidential Information of the Disclosing Party, except that one copy of such Confidential Information may be kept by the Receiving Party in its confidential files for record keeping purposes only.

13.5 Each Party will restrict the disclosure of Confidential Information to such officers, employees, consultants and representatives of itself and its Affiliates who have been informed of the confidential nature of the Confidential Information and who have a need to know such Confidential Information for the purpose of this Agreement. Prior to disclosure to such persons, the Receiving Party shall bind its and its Affiliates' officers, employees, consultants and representatives to confidentiality and non-use obligations no less stringent than those set forth herein. The Receiving Party shall notify the Disclosing Party as promptly as practicable of any unauthorized use or disclosure of the Confidential Information.

13.6 The Receiving Party shall at any time be fully liable for any and all breaches of the confidentiality obligations in this Clause 13 by any of its Affiliates or the employees, Subcontractors, consultants and representatives of itself or its Affiliates.

13.7 Each Party hereto expressly agrees that any breach or threatened breach of the undertakings of confidentiality provided under this Clause 13 by a Party may cause irreparable harm to the other Party and that money damages may not provide a sufficient remedy to the non-breaching Party for any breach or threatened breach. In the event of any breach and/or threatened breach, then, in addition to all other remedies available at law or in equity, the non-breaching Party shall be entitled to seek injunctive relief and any other relief deemed appropriate by the non-breaching Party.

14 Compliance

14.1 Lonza undertakes to conduct its business in accordance with all applicable laws and regulations and the principles in the Lonza Code of Conduct as can be found online at https://www.lonza.com/about-lonza/global-citizenship/ethics-and-compliance/code-of-conduct.asp.

14.2 Either Party is committed to maintaining high standards of ethical conduct and will not tolerate the use of bribery or corruption to achieve its business objectives. Thus, Lonza and Customer, including their affiliates, and their directors, employees, agents, representatives, contractors or sub-contractors, shall comply at all times with all applicable anti-bribery laws, rules and regulations (including but not limited to the UK Bribery Act and the United States Foreign Corrupt Practices Act (FCPA)) as well as any and all International Trade Restrictions. For the avoidance of doubt, this will include, not offering or giving a financial or other advantage with the intention of influencing in connection with the performance of the duties to obtain or retain a business advantage for Customer.

14.3 Each Party shall (and shall procure that its affiliates shall) have in place adequate procedures designed to prevent any person working for or engaged by such Party and its affiliates or any other third party in any way connected to this Agreement, from engaging in any activity, practice or conduct which would infringe any anti-bribery and anti-corruption laws, regulations and codes, including but not limited to the UK Bribery Act 2010 and the FCPA.

14.4 Each Party and its representatives shall at all times and promptly take all appropriate steps to resolve and correct any identified non-conformity. [***]. Subject to Clause 12, [***].

14.5 Upon request of a Party, the other Party shall promptly provide reasonably detailed information on its level of compliance with this Clause 14 so that the requesting Party can assess whether the other Party complies with the requirements or not.

15 Term and Termination

15.1 Term. This Agreement shall commence on the Effective Date and, unless earlier terminated or extended by the Parties in accordance herewith (subject to the rights of early termination set out herein), shall continue in effect until the seventh (7^{th}) anniversary of the first regulatory approval of the Drug Product manufactured by using the Product in the earlier of EU or the US (the “Initial Term”). Until two (2) years before the end of the Initial Term (i.e. estimated as [***]), Customer shall have the option, upon notification to Lonza, to extend the Agreement with another two (2) year term (“Renewal Term”) after expiry of the Initial Term (i.e. until approximately December 31, 2031). The Initial Term, together with the Renewal Term, if applicable, shall be defined as the “Term”. Notwithstanding the foregoing, each Project Plan or work order may have separate term and termination provisions.

15.2 Termination. This Agreement may be terminated as follows:

15.2.1 by either Party if the other Party breaches a material provision of this Agreement or a Project Plan and fails to cure such breach to the reasonable satisfaction of the non-breaching Party within [***] ([***]) days ([***] ([***]) days for non-payment) following written notification of such breach from the non-breaching party to the breaching party; provided, however, that such [***] ([***]) day period shall be extended as agreed by the Parties if the identified breach is incapable of cure within [***] ([***]) days and if the breaching Party provides a plan and timeline to cure the breach, promptly commences efforts to cure the breach and diligently prosecutes such cure (it being understood that this extended period shall be unavailable for any breach regarding non-payment);

15.2.2 by either Party, immediately, if the other Party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, or files or has filed against it, a petition in bankruptcy or has a receiver appointed for a substantial part of its assets;

15.2.3 by either Party pursuant to Clause 16;

15.2.4 by either Party with [***] ([***]) months' prior written notice, within [***] days following a Change of Control of the Customer, provided that (a) during such [***] ([***]) [***] period, Customer may place, and Lonza will accept, binding Purchase Orders in accordance with the provisions of Section 6.2, and (b) all Purchase Orders binding the Parties as of the end of such [***] ([***]) month period will remain binding on the Parties subject to the terms and conditions of Section 6 and (c) Customer shall remain to be bound by Section 6.5 and 6.6. For purposes of this section 15.2.4 "Change of Control" means the occurrence of any of the following with respect to Customer at any time after the date hereof: (a) a merger, reorganization or consolidation of Customer with a third party which results in the voting securities of Customer outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (b) a third party person or group of persons becoming the direct or beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding shares of common stock or other type of voting securities of Customer; or (c) the sale or other transfer of all or substantially all of Customer's assets which relate to this Agreement to a third party. Notwithstanding the foregoing, an internal reorganization or consolidation among Customer and its Affiliates shall not be deemed a Change of Control for purposes of this Agreement;

15.2.5 by Lonza by written notice if, [***], Lonza determines that in respect of the Product [***] (i) [***] and/or (ii) [***]. The termination right as per this Clause 15.2.5 is valid until [***] only, subject to an extension to be mutually agreed upon. After [***] (or any extension date agreed in this respect), Lonza shall have no right to terminate this Agreement on grounds [***] pursuant to this Clause 15.2.5; or

15.2.6 by the Customer by written notice, if Customer can demonstrate [***]. The termination right as per this Clause 15.2.6 is valid only if given [***], subject to an extension to be mutually agreed upon. After any notification to [***] or [***] (or any extension date agreed in this respect), Customer shall have no right to terminate this Agreement on grounds of [***].

15.3 Consequences of Termination. In the event of termination hereunder, Lonza shall be compensated for (i) [***]; (ii) [***]; (iii) [***]; (iv) [***] and (v) [***]. In the case of termination by Lonza for Customer's material breach, [***]. [***] if the Agreement is rightfully terminated in accordance with Clauses 15.2.5 or 15.2.6. If Lonza terminates this Agreement due to Customer's breach or insolvency in accordance with Clause 15.2.1 or 15.2.2, [***]. If the Customer terminates this Agreement due to Lonza's breach or insolvency in accordance with Clause 15.2.1 or 15.2.2, [***].

15.4 Survival. The rights and obligations of each Party which by their nature survive the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement, including Clauses 5, 10-13 and 17 (to the extent relevant).

16 Force Majeure

16.1 If Lonza is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure and gives written notice thereof to Customer specifying the matters constituting Force Majeure together with such evidence as Lonza reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue, Lonza shall be excused from the performance or the punctual performance of such obligations as the case may be from the date of such notice for so long as such cause of prevention or delay shall continue. Provided that, if such Force Majeure persists for a period of [***] ([***]) months or more, Customer may terminate this Agreement by delivering written notice to Lonza.

16.2 "Force Majeure" shall be deemed to include any reason or cause beyond Lonza's reasonable control affecting the performance by Lonza of its obligations under the Agreement, including, but not limited to, any cause arising from or attributable to acts of God, strike, lockouts, labor troubles, restrictive governmental orders or decrees, riots, insurrection, war, terrorists acts, or the inability of Lonza to obtain any required raw material, energy source, equipment or labor.

16.3 With regard to Lonza, any such event of Force Majeure affecting services or production at its Affiliates or suppliers shall be regarded as an event of Force Majeure.

17 Miscellaneous

17.1 Severability. If any provision hereof is or becomes at any time illegal, invalid or unenforceable in any respect, neither the legality, validity nor enforceability of the remaining provisions hereof shall in any way be affected or impaired thereby. The Parties hereto undertake to substitute any illegal, invalid or unenforceable provision by a provision which is as far as possible commercially equivalent considering the legal interests and the Purpose.

17.2 Amendments/Assignment. Modifications and/or amendments of this Agreement must be in writing and signed by the Parties. Lonza shall be entitled to instruct one or more of its Affiliates to perform any of Lonza's obligations contained in this Agreement, but Lonza shall remain fully responsible in respect of those obligations. Subject thereto, neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, provided, however that (a) Lonza may assign this Agreement to (i) any Affiliate of Lonza or (ii) any third party, other than a competitor of Customer, being [***], in connection with the sale or transfer (by whatever method) of all or substantially all of the assets of the business related to the Facility or providing the Services, and (b) Lonza shall be entitled to sell, assign and/or transfer its trade receivables resulting

from this Agreement without the consent of the Customer. Customer is free to assign its rights and obligations, including (without limitation) to a third party acquiring, by purchase or license, rights to further develop or commercialize Customer's [***] product, except to [***]. For purposes of this Clause 17.2, the terms "assign" and "assignment" shall include, without limitation (i) the sale of fifty percent (50%) or more of the outstanding stock of such Party to an Affiliate of such Party or an unrelated entity or natural person, (ii) the sale or transfer or other assignment of all or substantially all of the assets of the Party or the line of business or Product to which this Agreement relates, and (iii) a merger, consolidation, acquisition or other form of business combination. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

17.3 No Presumption Against Drafter. Each Party and its legal counsel have reviewed and revised this Agreement. The rule of construction that requires that ambiguities in this Agreement (including any Appendix hereto) be construed against the drafter shall be waived by both Parties in the interpretation of this Agreement.

17.4 Notice. All notices must be written and sent to the address of the Party first set forth above. All notices must be given (a) by personal delivery, with receipt acknowledged, (b) by prepaid certified or registered mail, return receipt requested, or (c) by prepaid recognized next business day delivery service. Notices will be effective upon receipt or at a later date stated in the notice.

17.5 Governing Law/Jurisdiction. This Agreement is governed in all respects by the laws of Switzerland without regard to its conflicts of laws principles. The United Nations Convention on Contracts for the International Sales of Goods is expressly disclaimed. The Parties agree to submit to the exclusive jurisdiction of the courts of [***].

17.6 Entire Agreement. This Agreement contains the entire agreement between the Parties as to the subject matter hereof and supersedes all prior and contemporaneous agreements with respect to the subject matter hereof. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. Each party acknowledges that an original signature or a copy thereof transmitted by .pdf shall constitute an original signature for purposes of this Agreement.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Tech Transfer and Manufacturing Services Agreement to be executed by its duly authorized representative effective as of the date written above.

LONZA LTD

By: /s/ Clemens Jakobi
Name Clemens Jakobi
Title Director, Commercial Director

By: /s/ Michael Stanek
Name Michael Stanek
Title General Counsel

ASCENDIS PHARMA A/S

By: /s/ Jan Møller Mikkelsen
Name Jan Møller Mikkelsen
Title CEO

ASCENDIS PHARMA A/S

By: /s/ Michael Wolff Jensen
Name Michael Wolff Jensen
Title Chief Legal Officer

APPENDIX A
Project Plan

APPENDIX B
Specifications

APPENDIX C
Initial Forecast as of the Effective Date

APPENDIX D
Prices

APPENDIX E
Raw Materials

APPENDIX F
CAPEX

APPENDIX G
Roadmap Cleanability

APPENDIX H
QUALITY AGREEMENT
(To be attached to the Agreement after finalization by the Parties)

APPENDIX A

Project Plan

Omitted pursuant to Regulation S-K, Item 601(a)(5)

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APPENDIX B

Specifications

Omitted pursuant to Regulation S-K, Item 601(a)(5)

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APPENDIX C

Initial Forecast as of the Effective Date

Omitted pursuant to Regulation S-K, Item 601(a)(5)

APPENDIX D

Prices

Omitted pursuant to Regulation S-K, Item 601(a)(5)

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APPENDIX E

Raw Materials

(Bill of Materials)

Omitted pursuant to Regulation S-K, Item 601(a)(5)

APPENDIX F

CAPEX

Omitted pursuant to Regulation S-K, Item 601(a)(5)

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APPENDIX G

Roadmap Cleanability

Omitted pursuant to Regulation S-K, Item 601(a)(5)

APPENDIX H

QUALITY AGREEMENT

Omitted pursuant to Regulation S-K, Item 601(a)(5)

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

PACKAGING AND SUPPLY AGREEMENT

This Packaging and Supply Agreement (the "Agreement") effective as of December 1, 2019 (the "Effective Date"), is entered into by and between Sharp Corporation, a corporation organized and existing under the laws of Pennsylvania having its principal office at 7451 Keebler Way, Allentown, Pennsylvania 18106 ("Sharp") and Ascendis Pharma A/S, a corporation organized and existing under the laws of Denmark having its principal office at Tuborg Boulevard 12, 2900 Hellerup, Denmark ("Ascendis") (hereinafter individually referred to as "Party" and collectively as "the Parties").

WITNESSETH:

WHEREAS, Ascendis desires to engage Sharp on a non-exclusive basis, to package the Product(s) (as defined below) and supply to Ascendis the Packaged Products (as defined below); and

WHEREAS, Sharp desires to accept such engagement under the terms and conditions set forth in this Agreement

NOW, THEREFORE, in consideration of these premises and the covenants, agreements and stipulations hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, agree as follows:

Definitions

1.1. "Affiliates" shall mean, any entities or persons directly or indirectly controlling, controlled by, or under common control with a party, where "controlled," "controlled by," and "under common control with" means the direct or indirect ability or power to direct or cause the direction of management policies of such entity or otherwise direct the affairs of such entity or person, whether through ownership of voting securities, by contract or otherwise.

1.2. "Applicable Law" shall mean the FDCA (as defined below) and all other laws, regulations, rules and guidelines promulgated by a Regulatory Authority in Exhibit E, Territory (as defined below), relating to the packaging of the Products and the storage and transportation of the Products or Packaged Products, including, but not limited to, current Good Manufacturing Practices ("cGMP") as specified in the United States Code of Federal Regulations, as amended from time to time. For purposes of this Agreement, the parties acknowledge and agree that notwithstanding anything to the contrary herein contained, [***].

1.3. “Brand Image” shall have the meaning set forth in Section 9.1.

1.4. “Carrier” or “Ascendis Carrier” shall mean a carrier engaged by Ascendis to ship Products in accordance with Section 6.2.

1.5. “Delivery” shall mean the transfer of Packaged Product at the point where risk and responsibility is transferred from Sharp to Ascendis according to the agreed Inco Terms, which shall be [***], [***].

1.6. “EMA” shall mean the European Medicines Agency, and any successor agency having substantially the same functions.

1.7. “Facilities” shall mean Sharp’s manufacturing facilities located at [***], and [***], and [***] and/or any other facility as may be designated by Sharp from time to time during the Term (as defined below) and approved by the Ascendis for use.

1.8. “FDA” shall mean the United States Food and Drug Administration, and any successor agency having substantially the same functions.

1.9. “FDCA” shall mean the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 et seq., as amended from time to time.

1.10. “Firm Order” shall mean a firm order as described in Section 5.2(b).

1.11. “Forecast” shall have the meaning set forth in Section 5.2(a).

1.12. “Packaging Materials” shall mean the components and other materials utilized by Sharp in connection with the packaging of the Products, which shall either be supplied by Ascendis or purchased by Sharp on Ascendis’ behalf.

1.13. “Packaged Product(s)” shall mean the Products in packaged form.

1.14. “Price” shall mean the price to be paid by Ascendis to Sharp for the Packaged Products and related services as set forth on Exhibit A, as may be adjusted in accordance with Section 6.1.

1.15. “Products” shall mean the products described on Exhibit A to be manufactured by or on behalf of Ascendis and shipped in bulk to Sharp for packaging. Upon the parties’ mutual written consent, the parties may from time to time during the Term amend Exhibit A to remove, add or substitute Products.

1.16. “Purchase Order” shall have the meaning set forth in Section 5.2(b).

1.17. “Quality Agreement” shall have the meaning set forth in Section 7.1.

1.18. “Regulatory Authority” shall mean any federal, state or local governmental regulatory authority in the Territory involved in regulating any aspect of the

development, market approval, sale, distribution or use of the Product, the Packaging Materials or the Packaged Product. For purposes of this Agreement, the parties acknowledge and agree that notwithstanding anything to the contrary herein contained, [***].

1.19. "Revised Purchase Order" shall have the meaning set forth in Section 5.2(b).

1.20. "Specifications" shall mean the specifications, provided by Ascendis to Sharp, to be followed by Sharp in connection with obtaining and using the Packaging Materials and the storage, labeling and packaging of the Products and the storage and supply of the Packaged Products. The Specifications are attached hereto as Exhibit B.

1.21. "Start-Up Activities" shall have the meaning set forth in Section 4.1.

1.22. "Term," "Initial Term" and "Subsequent Term" shall have the meanings set forth in Section 12.1.

1.23. "Territory" shall mean the countries listed in Exhibit E. More countries may be added to the Territory later upon mutual agreement.

1.24. "Tooling" shall mean the tooling made for the packaging, assembly, and labeling of the Products.

The definitions in this Article 1 shall apply equally to both the singular and plural forms of the terms defined. The words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation." All references herein to Sections and Exhibits shall be deemed references to Sections of this Agreement and Exhibits to this Agreement unless the context shall otherwise require.

2. Nature of Engagement

2.1 Engagement. Ascendis hereby engages Sharp, and Sharp hereby accepts Ascendis' engagement, as Ascendis' service provider to store, package, assemble, and label the Products and store and supply the Packaged Products for commercial use within the Territory in accordance with the Specifications and the terms and conditions of this Agreement.

2.2 Independent Contractor. Sharp shall be deemed an independent contractor with respect to the terms and provisions of this Agreement and shall not in any respect be deemed an agent or employee of Ascendis. All persons employed by Sharp in connection with the storage, labeling, packaging, assembly, and supply of the Products and/or the Packaged Products, as applicable, to Ascendis shall be employees or agents of Sharp. Under no circumstances shall Sharp or any of its employees or agents be deemed to be employees or agents of Ascendis.

3. Governance.

3.1 The Parties shall form a Joint Steering Committee ("JSC") comprising of [***] ([***]) or [***] ([***]) members from each Party, including at least [***] ([***]) member of

each Party's senior management. The JSC shall meet [***] ([***]) times per [***] to discuss and evaluate the mutual collaboration and shall in good faith attempt to resolve any disputes in connection with the Agreement. Each Party may call for an ad hoc teleconference as such Party deems necessary. As agreed between the Parties in each case, the meetings of the JSC may be carried out by teleconference, video conference or face-to-face, as the case may be, provided however that the Parties endeavor to meet face to face at least [***] per [***]. Decisions in the JSC must be unanimous. If this is not possible, the dispute must be referred to Sharp and Ascendis executive management for negotiation.

3.2 Written minutes of JSC meetings must be made alternately by each Party, or as agreed from time to time, and must be circulated for comments no later than [***] ([***]) [***] after each meeting.

3.3 Sharp shall appoint an Account Manager and Ascendis shall appoint a primary logistics contact who shall both act as single point of contact for the other Party in operational matters, except for quality related issues, which shall be governed in accordance with the Quality Agreement. The Sharp Account Manager and Ascendis' primary logistics contact shall engage vi teleconference at regular intervals to be mutually agreed.

4. Start-Up Activities.

4.1 Start-Up Activities. As used in this Agreement, "Start-Up Activities" shall mean those activities that Ascendis and Sharp agree are necessary to commence packaging of the Products. Sharp shall complete the Start-Up Activities in accordance with the project timeline agreed to in writing by the parties. Any protocols and reports prepared by Sharp in connection with the Start-Up Activities shall be subject to Ascendis' prior review and approval, which approval shall not be unreasonably withheld, conditioned or delayed. Sharp shall permit a representative of Ascendis to observe and review the Start-Up Activities at the relevant Facilities during normal business hours and upon reasonable notice. The validation reports produced in connection with the Start-Up Activities shall be deemed Confidential Information of Sharp subject to Article 13 of this Agreement and shall be made available for Ascendis upon request. The costs associated with the Start-Up Activities shall be as agreed upon by the parties and shall be borne [***].

4.2 Purchase and Installation of Equipment, Molds and Tooling. Sharp shall be responsible for installing at its Facilities any and all new equipment, molds and/or modifications to existing equipment and molds deemed necessary by Sharp for the packaging, assembly and labeling of the Products and for preparing the Packaged Products for shipment, and all costs and expenses associated therewith; provided, however, that Ascendis shall be responsible for the costs and expenses associated with the development and manufacturing of the Tooling and any equipment other than Tooling purchased exclusively for use under this Agreement ("Ascendis Specific Equipment"), as listed in Exhibit F. Sharp shall insure, maintain and store at its own cost the Tooling and Ascendis Specific Equipment at the Facilities while Ascendis shall retain all right, title and interest in and to the Tooling and Ascendis Specific Equipment during and after the Term. Sharp shall not modify the Tooling or the Ascendis Specific Equipment without the consent of Ascendis, such consent not to be unreasonably withheld, conditioned or delayed. Upon the expiration or termination of this Agreement, Sharp shall deliver all Tooling and Ascendis Specific Equipment to Ascendis.

5. Agreement to Supply; Forecasts; Purchase Orders.

5.1 Generally. During the Term, Sharp shall store, package, assemble and label the Products and store and supply to Ascendis the Packaged Products, all in accordance with the Specifications and the terms of this Agreement, and Ascendis shall pay for the Packaged Products in accordance with Article 5 of this Agreement.

5.2 Forecasts and Purchase Orders.

(a) Beginning on the Effective Date and thereafter on or prior to the [***] preceding each [***] month of the Term, Ascendis shall provide Sharp with a [***] ([***]) month rolling forecast (each, a "Forecast") of Ascendis' quantity and Delivery date requirements for the Packaged Products.

(b) The first [***] ([***]) months of each Forecast shall constitute a firm order ("Firm Order") and shall be binding upon Ascendis (whether or not Sharp receives a Purchase Order in connection with such [***] period). For the purposes of ordering packaging materials and scheduling capacity, Ascendis shall provide Sharp with purchase orders (each, a "Purchase Order") in connection with each such [***] ([***]) month Firm Order period for the Packaged Products to be supplied during that period. Every Purchase Order shall specify the quantities and Delivery dates for the Packaged Products for the applicable Firm Order period. So long as the quantity and Delivery date requirements set forth in the Purchase Orders during any [***] ([***]) month Firm Order period are consistent with the applicable Firm Order, Sharp shall respond with an order acknowledgment within [***] ([***]) business days. If the quantity and Delivery date requirements set forth in the Purchase Orders are not consistent with the applicable Firm Order, or in the event that Ascendis desires to subsequently amend a Purchase Order, then the parties shall cooperate in good faith to issue and substitute a mutually agreeable revised Purchase Order (a "Revised Purchase Order") at least [***] ([***]) days prior to the scheduled start of the relevant production; provided, however that Sharp, prior to the agreement on a Revised Purchase Order, shall inform Ascendis of any Price implications as per section 6.1 (a) (i); and provided also that in the event a Revised Purchase Order is not agreed upon by the parties, Ascendis shall be obligated to purchase all Packaged Products arising from the applicable Firm Order.

(c) Nothing printed or written on any Purchase Order, Sharp order acknowledgement or on any other similar form or document shall modify or expand either party's obligations under this Agreement, and any pre-printed terms and conditions contained in any such Purchase Order, order acknowledgement or other such form or document shall not apply.

5.3 Production Requirements. Subject to the terms of this Agreement, Sharp shall (a) devote the necessary production capacity to fulfill the quantity and Delivery date requirements set forth in each confirmed Purchase Order, and (b) [***] make available sufficient additional production capacity, subject to overtime charges set forth in Exhibit A, to support all Forecasts; provided, that the parties shall cooperate in good faith to reach a mutually agreeable accommodation [***].

5.4 Ascendis' Supply Obligations. Sharp's obligations to fulfill any Purchase Order are subject to Ascendis' obligation to provide Sharp with the following items within the following time periods:

(a) At least [***] ([***]) weeks prior to Sharp's commencement of the production of the Packaged Products, any text, graphics or other artwork to be printed by Sharp on the Packaging Materials, all of which shall be in conformity with all Applicable Laws;

(b) At least [***] ([***]) weeks prior to Sharp's commencement of the production of the Packaged Products, any Packaging Materials that are to be supplied by Ascendis;

(c) At least [***] ([***]) weeks prior to Sharp's commencement of the production of the Packaged Products, the lot and expiry information for the Products; and

(d) At least [***] ([***]) weeks prior to Sharp's commencement of the production of the Packaged Products, the Products.

5.5 Storage Facilities; Inventory. Sharp shall store Products and Packaged Products at its Facilities under conditions as specified in the Quality Agreement, and including such security measures as [***]. Sharp agrees to provide adequate storage space for the Products and the Packaged Products. Upon Ascendis' request, and, if stored for more than [***], subject to storage charges at the rates specified in Exhibit A, Sharp shall store Products for Ascendis until the Products expire, are consumed in production, or otherwise used. Sharp will maintain adequate inventories of materials on hand or with suppliers to accommodate reasonable variations in packaging that may be required by Ascendis hereunder. Sharp shall store and deliver Packaged Product to Ascendis in accordance with the Specifications, and pursuant to the terms and conditions set forth in this Agreement, including, but not limited to, Sections 5.2 and 5.4 hereof. Upon Ascendis' request, Sharp shall store Packaged Products for Ascendis until the Products are shipped, expire or otherwise used, in which case Sharp shall charge Ascendis for storage in accordance with its storage rates, as specified in Exhibit A. Sharp shall at the end of each [***] send Ascendis an inventory report of Products and Packaged Products held at the Facilities.

5.6 Packaged Product Samples. Sharp shall provide Ascendis with representative lot samples of Packaged Products promptly upon request. Such Packaged Product samples shall be shipped to Ascendis in accordance with the provisions set forth in Section 6.2.

5.7 Serialization. Sharp shall provide to Ascendis the serialization services and maintenance parameters more specifically set forth in Exhibit A-1, at the Price and subject to the additional terms and conditions provided for therein.

6. Price; Payment; Delivery.

6.1 Determination of Prices.

(a) The Price to be paid to Sharp by Ascendis for the supply of the Packaged Products shall be as set forth on Exhibit A. The first review of pricing will occur [***] months prior to Ascendis' expected launch date. Thereafter, the Parties will review the Price on an [***] basis. Sharp shall submit to Ascendis revised pricing, reflecting (aa) [***], or (ab) [***], or (ac) [***]. Ascendis and Sharp shall execute an amended Exhibit A to this Agreement to reflect the adjustment to the Price. The foregoing notwithstanding, Sharp may adjust the Prices set forth on Exhibit A at any time during the Term, in accordance with the following:

(i) Subject to prior information as per 5.2 (b), [***];

(ii) In the event that [***], the parties agree [***]; and

(iii) In the event that [***], [***].

(b) Prior to the commencement of any Subsequent Term, the parties shall negotiate in good faith the Price that shall apply to such Subsequent Term. The parties shall take into account in any such negotiations [***], and, Sharp agrees that it shall not increase the cost of labor applicable to a Subsequent Term more than [***] per [***], and Sharp shall not increase the cost of materials more frequently than [***] every [***]. .

(c) The Prices set forth on Exhibit A do not include sales, use, consumption, ad valorem, VAT or excise taxes of any taxing authority. The amount of such taxes, if any, will be added to the Price of the Packaged Products in effect at the time of shipment thereof and shall be reflected in the invoices submitted to Ascendis by Sharp pursuant to Section 6.3. Ascendis shall pay the amount of such taxes to Sharp in accordance with the payment provisions relating to shipments of Packaged Products set forth in Section 6.3.

6.2 Delivery. Sharp shall Deliver Packaged Product to Ascendis' designee [***] (Incoterms 2010), at [***], packed in accordance with the requirements set out in the Quality Agreement. Sharp shall arrange for the shipment of the Packaged Products with Ascendis Carriers. Ascendis shall pay outbound freight delivery costs as part of the price, according to Exhibit A. Ascendis shall from time to time audit its approved carriers in accordance with Ascendis' policies. As part of such audit(s), Ascendis agrees to [***]. In addition, Ascendis shall use only carriers who have agreed to comply with all Applicable Laws and any other applicable federal, state and local laws and regulations.

6.3 Invoices. Sharp shall submit invoices to Ascendis for all Deliveries of Packaged Products hereunder (i) upon Delivery of such Packaged Products to Ascendis' designee, or (ii) upon placement, per Ascendis' request, of released Packaged Products into storage at the Facilities. Invoices shall be directed by Sharp personnel to Ascendis' Accounts Payable Department ([***]@ascendispharma.com), or to such other persons, departments or locations as Ascendis may instruct in writing from time to time. Invoices shall clearly state quantity, price and batch numbers, and shall reference the relevant Purchase Order. Each invoice shall be payable within [***] ([***]) days of the date of such invoice.

6.4 Risk of Loss. Title to all Products, Packaged Products, all work in process to produce Packaged Products and/or any other property of Ascendis ("Ascendis Property") shall at all times remain with Ascendis. Sharp shall not be liable for risk of loss to any Ascendis' Property, except in the case of negligence, gross negligence or willful misconduct by Sharp. The foregoing notwithstanding, Sharp's [***] liability under this Agreement as it relates to Ascendis Property shall not exceed [***] Dollars ($[***]) in the case of negligence, gross negligence or willful misconduct.

6.5 Non-Conforming Packaged Products and Quantitative Defects. Ascendis shall have the right, within [***] ([***]) days following Sharp's Delivery of Packaged Products to the Ascendis Carrier, to give Sharp written notice of rejection of the portion of such shipment of Packaged Products that fails to meet the Specifications, or which otherwise breaches Sharp's covenants and obligations under this Agreement. Sharp, at its sole cost and expense, shall provide Ascendis with any missing quantities and/or replace as soon as [***] any packaging services for any non-conforming Packaged Products [***]. Any claim of a non-conforming shipment must be made in writing to Sharp within the [***] ([***]) day period set forth above or it shall be deemed to have been waived by Ascendis.

6.6 Target Yield Rate. Sharp and Ascendis agree to evaluate the amount of drug loss after Sharp performs the services to produce [***]. After the completion of the [***], the Parties shall analyze the yield rate for those [***], and agree to a Target Yield Rate that will apply to the remaining Services, which will consider any samples or other related issues that arise with the [***] runs. For lots manufactured after the first [***], Sharp shall reimburse Ascendis for drug loss stemming from a shortfall between the actual yield rate and the Target Yield Rate, subject to the general liability cap pursuant to Section 6.4, calculated by using the [***] manufacturing cost of the Product, [***]. Ascendis and Sharp agree to on an annual basis mutually review whether the [***] is materially different from the [***] manufacturing cost and if necessary to discuss in good faith any adjustments needed.

7. Quality Control; Access; Inspection; Samples.

7.1 Quality Agreement. The parties have entered into a quality agreement with respect to the quality assurance and packaging of Product by Sharp hereunder, which is referenced in Exhibit D ("Quality Agreement"). In the event there is any conflict relating to quality control procedures or cGMP-related activities between the terms and provisions of this Agreement and the Quality Agreement, the applicable terms and provisions of the Quality Agreement shall control and prevail; provided that, with respect to all other matters, the terms, provisions and conditions of this Agreement shall control and prevail.

7.2 Release. Sharp shall perform its own release of the Packaged Products. No later than [***] days prior to the confirmed date of Delivery, Sharp shall forward such documentation as necessary for Ascendis to perform final release (the "Release Documentation") to Ascendis. The requirements for Release Documentation shall be specified in the Quality Agreement. Final Release shall be performed by Ascendis' Qualified Person, such Final Release not to be unreasonably withheld. Delivery is subject to Final Release except in the event that Ascendis requests for shipment in Quarantine (as defined in the Quality Agreement).

7.2 Modification of Specifications. The Specifications may not be modified or changed without the mutual written agreement of the parties.

7.3 Storage Requirements. Sharp shall use the Products and the Packaging Material on a first in, first out basis, unless otherwise instructed by Ascendis in writing, and shall not use either the Products or the Packaging Material beyond the shelf life required under any Applicable Law.

7.4 Notices Regarding Packaging Materials. Sharp shall promptly contact Ascendis, care of Ascendis' Quality Assurance Department (or such other persons or departments as Ascendis may instruct), in the event that Sharp anticipates making changes to any Packaging Material or in the event Sharp considers any current Packaging Material to be nonconforming with the Specifications or Applicable Law.

7.5 Quality Inspections. Sharp shall perform certain in-coming, in-process and finished product inspections necessary to assure the quality of the Packaging Material and Packaged Products as provided for in Sharp's standard procedures and any inspections required by Applicable Law of the United States or as otherwise required by the Specifications. For purposes of this Agreement, inspections performed [***] shall be considered routine and shall be performed at Sharp's expense. [***] will be completed at cost and at Ascendis' expense. All inspections and related results shall be performed, documented and summarized by Sharp in accordance with Sharp's standard procedures, the Specifications and Applicable Law of the United States. The parties hereto will negotiate in good faith any unanticipated burdens resulting from changes made to any Applicable Law after the Effective Date.

7.6 Records. For the period set forth in Section 7.10, Sharp shall maintain detailed records on Packaging Material usage and Packaged Product production, including lot numbers, serial numbers, and shipping information relating to the Packaged Products, so that the Packaged Products can be traced in case of a recall. Sharp's Packaged Product records shall be sufficient such that Sharp shall be capable of responding to Packaged Product inquiries by Ascendis within [***] ([***]) hours following notification, including providing the lot numbers and the location within the Facilities of the Packaged Products in question.

7.7 Recalls. Ascendis shall have sole responsibility for initiating and managing any recall or withdrawal of the Packaged Products, and shall bear all costs and expenses relating thereto. Upon receiving from any Regulatory Authority having jurisdiction any direction to withdraw or recall any Packaged Product from the market, the receiving party shall promptly notify the other party. [***] Sharp shall provide such assistance as Ascendis may reasonably request in connection with any such withdrawal or recall. Ascendis shall provide copies of Field Alerts (initial and final), Recalls, Medical Assessments and/or follow-up reports to Sharp within [***] ([***]) [***] days. Sharp shall have no liability with respect to any recall or withdrawal of Packaged Products except to the extent arising directly from Sharp's negligence, gross negligence or willful misconduct, in which case Sharp's liability shall be limited to [***] Dollars ($[***]) per recall.

7.8 Maintenance of Facilities. In the event Sharp fails or anticipates it will fail to maintain the Facilities in accordance with the Specifications and all Applicable Laws of the

United States, or in the event Sharp receives any notice from any Regulatory Authority of the United States with respect to its maintenance of the Facilities, and only if such maintenance or notice affects the Products, Sharp shall promptly notify Ascendis, care of Ascendis' Quality Assurance Department (or such other persons or departments as Ascendis may instruct), provide copies of such notice to Ascendis and, if such Regulatory Authority notice relates specifically to the Packaged Products, provide a copy of Sharp's response to such Regulatory Authority.

7.9 Inspections and Audits. Ascendis and all Regulatory Authorities shall have access at reasonable times and with reasonable frequency to Sharp's Facilities where Products are located for the purpose of conducting inspections of, performing quality control audits with respect to, or witnessing, the processing, storage or transportation of Products, Packaged Products or Packaging Materials, and Ascendis shall have access at reasonable times and with reasonable frequency to the results of any inspections relating to the Products that are performed by Sharp or at Sharp's direction. Sharp shall use its reasonable efforts to cause Sharp's suppliers or agents to permit Ascendis similar access to their respective facilities, data and records. Such inspections, audits and visits shall be conducted by Ascendis' personnel upon reasonable notice and during normal business hours. Sharp shall be entitled to charge a fee for hosting Regulatory Authority audits from [***], unless such audits are "for cause" due to quality issues.

7.10 Retention of Samples and Records. Sharp shall retain and, upon request by Ascendis at reasonable times and with reasonable frequency, make available to Ascendis, (a) copies of the quality control records maintained in accordance with Section 7.6 and otherwise in relation to the Packaged Products, (b) copies of inspection results of all the inspections performed in relation to the Packaged Products, (c) records of each batch of Packaged Product and (d) samples of the Packaging Materials and Packaged Product, upon reasonable request. All quality control and assurance records and samples will be maintained by Sharp for [***] ([***]) year following the Packaged Product expiration date or such longer time period as may be required by Applicable Law of the United States.

7.11 Government Inspections, Seizures and Recalls. If any Regulatory Authority makes an inspection at Sharp's Facilities, seizes Products or Packaged Products or requests a recall of Packaged Products, Sharp shall promptly notify Ascendis' Quality Assurance Department (or such other persons or departments as Ascendis may instruct), and Sharp shall take such actions as may be required under the Specifications or as may be reasonably requested in writing by Ascendis; [***]. Sharp shall promptly send duplicate reports relating to such inspections to Ascendis care of Ascendis' Quality Assurance Department (or such other persons or departments as Ascendis may instruct).

7.12 Legal and Regulatory Filings and Requests. Sharp and Ascendis shall cooperate and be diligent in responding to all requests for information from, and in making all required filings, [***], with any Regulatory Authority having jurisdiction to make such requests or require such filings. Sharp shall, [***], obtain and comply with all licenses, consents, permits and regulations which may from time to time be required by an appropriate Regulatory Authority of the United States with respect to the performance of its obligations hereunder.

7.13 Complaints. In connection with any Packaged Product complaints reasonably relating to packaging services that are forwarded by Ascendis to Sharp, Sharp shall conduct a [***] investigation of such complaint, at no additional cost to Ascendis.

8. Warranties; Limitation of Liability.

8.1 General Warranties. Sharp warrants that: (a) the Products shall be stored, processed, packaged and labeled in accordance with the Specifications and all Applicable Laws of the United States; (b) the Packaged Products furnished by Sharp to Ascendis under this Agreement (i) shall be at the time of Delivery to a Ascendis Carrier of the quality specified in, and shall conform with, the Specifications for packaging and any Applicable Law of the United States, (ii) shall be stored and supplied in conformity with the Specifications and any Applicable Law of the United States and (iii) shall not contain any material provided by or on behalf of Sharp, which material has not been used or stored in accordance with the Specifications and any Applicable Law of the United States; (c) it will not introduce any materials not provided for in the Specifications that would cause the Packaged Products to be adulterated within the meaning of Section 501 of the FDCA; and (d) the Packaged Products shall not be misbranded by Sharp within the meaning of the FDCA ([***]). Any claim by Ascendis for breach of warranty that is not brought before the expiry of the applicable Packaged Product shall be deemed to have been waived by Ascendis.

8.2 Disclaimer; Limitation of Liability. NOTWITHSTANDING ANYTHING ELSE IN THIS AGREEMENT TO THE CONTRARY THE WARRANTIES WITH RESPECT TO THE STORING, PACKAGING, ASSEMBLY, LABELING AND DELIVERY OF THE PRODUCTS AND THE PACKAGED PRODUCTS STATED IN THIS ARTICLE 8 ARE IN LIEU OF ALL OTHER WARRANTIES OF SHARP, ORAL OR WRITTEN, EXPRESSED OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED FOR HEREIN, IN NO EVENT SHALL [***] AGGREGATE LIABILITY EXCEED [***] DOLLARS ($[***]) [***] HAVE ANY LIABILITY FOR ANY EXEMPLARY, PUNITIVE, INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON CONTRACT, TORT, STRICT LIABILITY OR ANY OTHER THEORY OR FORM OF ACTION [***]. [***].

9. Intellectual Property Rights.

9.1 Intellectual Property Rights of Ascendis; Grant of License. Except as specifically set forth in Section 9.2, [***]. Ascendis hereby grants to Sharp a [***] as may be necessary for Sharp's fulfillment of its services in accordance with this Agreement (including in accordance with the Specifications) [***]. Except as set forth in the immediately preceding sentence, Sharp shall have no other rights to use the Brand Image.

9.2 Ownership of Other Property. All right, title and interest in and to (a) [***], (b) [***], and (c) [***]. Nothing in this Agreement shall be construed to grant to Ascendis any right to any trademark, trade name, copyright, patent or other proprietary technology or know-how owned by Sharp.

10. Indemnification.

10.1 Sharp's Indemnification of Ascendis. Sharp shall defend, indemnify and hold Ascendis and its officers, directors and employees (each, a "Ascendis Indemnified Party") harmless from and against any and all losses, liabilities, damages, claims for damages, suits, recoveries, judgments or executions resulting from a third party claim (including reasonable attorneys' fees and expenses) (collectively, "Damages") that may be incurred by any Ascendis Indemnified Party arising out of or on account of: (a) [***]; or (b) [***].

10.2 Ascendis' Indemnification of Sharp. Ascendis shall defend, indemnify and hold Sharp and its Affiliates and the officers, directors and employees thereof (each, a "Sharp Indemnified Party") harmless from and against any and all Damages that may be incurred by any Sharp Indemnified Party arising out of or on account of: (a) [***]; (b) [***]; (c) [***]; (d) [***]; or (e) [***].

10.3 Indemnification Procedure. Any party seeking indemnification in accordance with this Article 10 (the "Indemnified Party") shall notify in writing the other party from whom such indemnification is sought (the "Indemnifying Party") of any third party claim made against the Indemnified Party, specifying the basis given by such third party of such claim. The Indemnified Party shall thereupon give the Indemnifying Party reasonable access to the books, records and assets of the Indemnified Party which evidence, support or directly relate to such claim. The Indemnifying Party shall have the right, upon giving written notice to the Indemnified Party within [***] ([***]) [***] days after the receipt of any such notice of claim, to undertake the defense of or, with the consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed), to settle or compromise such claim. The failure of the Indemnifying Party to give such notice and to undertake the defense of or to settle or compromise such a claim shall constitute a waiver of the Indemnifying Party's rights under this Section 10.3 [***]; provided however, that the Indemnified Party shall not settle or compromise such claim without the prior written approval of the Indemnifying Party (which approval shall not be unreasonably withheld, conditioned or delayed). The election by the Indemnifying Party, pursuant to this Section 10.3 to undertake the defense of a third-party claim shall not preclude the party against which such claim has been made also from participating or continuing to participate in such defense, so long as such party bears its own legal fees and expenses for so doing.

10.4 Survival. The indemnification obligations set forth in this Article 10 shall survive the expiration or termination of this Agreement.

11. Insurance.

Sharp shall acquire and maintain at its sole cost and expense: (a) Statutory Worker's Compensation Insurance and Employer's Liability Insurance; (b) risk coverage of not less than [***] dollars ($[***]) for physical loss or damage to materials including Products and Packaged Products while at the Facilities or under its control; and (c) products liability, bodily injury and property damage insurance with a combined single limit of not less than [***] dollars ($[***]).

12. Term; Termination.

12.1 Initial Term; Term. The initial term of this Agreement shall begin on the Effective Date and shall terminate on December 31, 2025 (the "Initial Term"). This Agreement will be automatically extended for additional two-year periods (such additional periods are each a "Subsequent Term," and collectively with the Initial Term, the "Term"). The Term shall end upon the expiration of this Agreement or its earlier termination as set forth in Section 12.2.

12.2 Termination. This Agreement may be terminated upon the occurrence of any of the following:

(a) The parties may terminate this Agreement by mutual written consent at any time;

(b) Either party may terminate this Agreement by giving thirty (30) days written notice to the other party in the event the other party has breached any representation, warranty or obligation contained in this Agreement and/or has defaulted in the performance of any of its duties or obligations hereunder in any material respect and such breach or default has not been remedied within thirty (30) days after written notice of the breach or default has been received;

(c) Either party may terminate this Agreement if a voluntary petition in bankruptcy should be filed by the other party under the United States Bankruptcy Code, if an involuntary petition under the United States Bankruptcy Code should be filed against the other party, or if a receiver should be appointed for the other party or its property;

(d) Either party may terminate this Agreement pursuant to Section 14.2.

(e) Ascendis may terminate this Agreement without cause by giving one (1) year's notice to Sharp. Sharp may terminate this Agreement without cause by giving two (2) years' notice to Ascendis. In both cases however, such termination can take effect no earlier than by the expiry of the Initial Term.

12.3 Effect of Expiration or Termination.

(a) The expiration or termination of this Agreement shall not release either party from any of its obligations accrued prior to the effective date of termination, and each party shall remain responsible for the performance of its respective obligations and agreements which are expressly stated to be obligations which survive the termination of this Agreement. Furthermore, the rights to terminate provided for hereinabove are in addition to any other right, remedy, or election either party may have hereunder or at law or in equity.

(b) Within [***] ([***]) days of the effective date of the expiration or termination of this Agreement for any reason, Ascendis shall purchase any Packaging Materials that Sharp has purchased exclusively for Ascendis in accordance with this Agreement for the production of the Packaged Products.

(c) Upon the effective date of expiration or termination of this Agreement, Sharp shall immediately deliver to Ascendis or its designee all Products, and all text, graphics and other artwork and Packaging Materials purchased or provided by Ascendis. Sharp shall also deliver to Ascendis or its designee all Packaged Products produced hereunder, and shall invoice Ascendis therefor in accordance with the terms of Section 6.3.

(d) Upon termination or expiration of this Agreement and upon the written request of Ascendis, Ascendis and Sharp will enter into a tech transfer agreement ("TTA"), under which Sharp provides necessary support and assistance enabling Ascendis to obtain continued supply of Packaged Product from an alternate supplier. The costs and expenses of such tech transfer shall be agreed upon in such TTA [***].

13. Confidentiality.

(a) Confidentiality. Sharp and Ascendis agree to keep secret and confidential any and all proprietary and non-public information of the other party ("Confidential Information") disclosed by the other party hereunder or through any prior disclosure and not to disclose such Confidential Information to any person or entity, except: (i) to Affiliates; provided that such Affiliates are made aware of the confidential nature of the Confidential Information and agree to comply with the terms of this Agreement; (ii) to employees and authorized representatives of each party having a need to know the information in order to fulfill such party's obligations hereunder; or (iii) as required by an applicable Regulatory Authority. The parties shall use the Confidential Information solely for the purpose of carrying out the obligations contained in the Agreement. The obligations imposed by this Section shall not apply to any Confidential Information:

(i) that, at the time of disclosure, is in the public domain;

(ii) that, after disclosure, becomes part of the public domain by publication or otherwise, through no fault of the recipient;

(iii) that, at the time of disclosure, is already in the recipient's possession, except through prior disclosure by the disclosing party, and such possession can be properly documented by the recipient in its written records, and was not made available to the recipient by any person or party owing an obligation of confidentiality to the disclosing party;

(iv) that is rightfully made available to the recipient from sources independent of the disclosing party;

(v) that is required to be disclosed in the course of litigation or other legal or administrative proceedings; provided that in all such cases the party receiving the Confidential Information shall, to the extent permitted, give the other party prompt notice of the pending disclosure and shall cooperate in such other party's attempts, at such other party's sole expense, to seek an order maintaining the confidentiality of the Confidential Information; or

(vi) that is required to be disclosed by Applicable Laws; provided that in all such cases the party receiving the Confidential Information shall, to the extent permitted, give the other party prompt notice of the pending disclosure and shall cooperate in such other party's attempts, at such other party's sole expense, to seek an order maintaining the confidentiality of the Confidential Information.

(b) Survival. The obligation of confidentiality and nonuse set forth in this Article 13 shall survive for a period of [***] ([***]) years beyond the termination or expiration of this Agreement.

(c) Ownership of Confidential Information. Confidential Information shall remain the exclusive property of the disclosing party. In no event shall any of either party's Confidential Information, technology, know-how, intellectual property (or rights thereto) become the property of the other party.

(d) [***] Consent. [***] shall not release to any third party any non-public information with respect to the terms of this Agreement without the prior written consent of [***].

(e) If a party concludes that a copy of this Agreement must be filed with the United States Securities Exchange Commission or other regulatory agency ("SEC") (or equivalent foreign agency or a securities exchange), such party will use [***] to provide the other party with a copy of this Agreement showing any provisions hereof as to which the party proposes to request confidential treatment, and to provide the other party with an opportunity to comment on any such proposed redactions and to suggest additional redactions. The filing party will take such other party's [***] comments into consideration before filing the Agreement.

14. Miscellaneous.

14.1 Authority to Enter Into Agreement. Each party represents and warrants that it is authorized to enter into this Agreement and that in so doing it is not in violation of the terms and conditions of any contract or other agreement to which it may be a party.

14.2 Force Majeure. Performance under this Agreement (other than performance of payment obligations) shall be excused to the extent prevented or delayed by any event or circumstance, which is beyond the reasonable control of the party whose performance is to be excused hereunder, including but not limited to fire, flood, explosion, widespread product tampering by third parties, governmental acts or regulations, war, labor difficulties, shortages or unavailability of materials, or any act of God. The party affected shall promptly notify in writing the non-affected party of the event of force majeure and the probable duration of the delay. Any delay caused by an event of force majeure happening within the Initial Term shall toll the Initial Term, which shall be extended by the length thereof. In the event a force majeure prevents performance by one party for more than [***] ([***]) months, either party may terminate this Agreement.

14.3 Public Announcements. The parties agree to determine jointly the contents of any public announcement informing the public about the existence of this Agreement between the parties and, except as may be required by law or the rules of any national securities exchange, neither party shall issue or cause the issuance of any such public announcement without the express prior approval of an executive officer of each party.

14.4 Amendments. Except to the extent otherwise provided in Section 6.1 of this Agreement with respect to amendments to Exhibit A, this Agreement may not be modified, amended or altered except pursuant to a written instrument signed by both parties.

14.5 Governing Law. This Agreement is made subject to the laws of the State of Delaware, without reference to principles of conflicts of laws. Each party agrees that suit may be instituted at any federal court in the Eastern District of Pennsylvania or in state court in Lehigh County in the Commonwealth of Pennsylvania and each waives any objection which such party may now or hereafter have to the laying of the venue of any such action, suit or proceeding, and irrevocably submits to the jurisdiction of any such court. Any and all service of process and any other notice in any such action, suit or proceeding shall be effective against a party if given as provided in Section 14.7. Nothing contained herein shall prevent or delay either party from seeking, in any court of competent jurisdiction in Pennsylvania, specific performance or other equitable remedies in the event of any breach or intended breach by the other party of any of its obligations hereunder.

14.6 Assignment. Neither party may, without the prior written consent of the other party, delegate, transfer, convey, assign or pledge any of its rights or obligations under this Agreement to any other person, firm or corporation; provided however, that such consent shall not be unreasonably withheld and provided further that neither party need to obtain any consent in the event a party assigns this Agreement to an entity that succeeds to all or substantially all of such party's business or assets. Additionally, Ascendis is free to assign its rights and obligations, including (without limitation) to a third party acquiring, by purchase or license, rights to further develop or commercialize Product.

14.7 Notice. Any and all notices permitted or required to be given hereunder will be deemed duly given: (a) upon actual delivery, if delivery is by hand; (b) [***] ([***]) [***] days after delivery into the United States Postal Service mail, if delivery is by postage paid registered or certified return receipt request mail; (c) [***] ([***]) [***] day after delivery to a nationally recognized overnight carrier, if delivery is made by [***] carrier guaranteeing [***] day delivery; or (d) upon receipt of evidence of successful transmission, if delivery is by facsimile. Each such notice shall be sent to the respective party at the address or facsimile number indicated below or at any other address as the respective party may designate by notice delivered pursuant hereto.

If to Ascendis:

Ascendis Pharma A/S
Tuborg Boulevard 12, 2900 Hellerup, Denmark
Attention: General Counsel

If to Sharp:

SHARP CORPORATION
7451 Keebler Way
Allentown, Pennsylvania 18106
Attention: CFO
Telecopier Number: (610) 254-1765

14.8 Compliance with Laws. In the performance of this Agreement, both parties agree to comply with all applicable federal, state or local laws, statutes, rules, regulations and ordinances, including any Applicable Laws, subject to any specific limitations set forth herein.

14.9 Entire Agreement. This Agreement, including all Exhibits attached hereto and made a part hereof, contains the entire understanding of the parties, superseding in all respects any and all prior oral or written agreements or understandings pertaining to the subject matter hereof, and except as otherwise specifically provided for herein, shall be amended or modified only by written agreement executed by the parties hereto. Delivery by reliable electronic means, including facsimile or email, shall be an effective method of delivering the executed Agreement. This Agreement may be stored by electronic means and either an original or an electronically stored copy of this Agreement can be used for all purposes, including in any proceeding to enforce the rights and/or obligations of the parties to this Agreement.

14.10 Severability. If and to the extent that any court of competent jurisdiction holds any provision or part of this Agreement to be invalid or unenforceable, such holding shall in no way affect the validity of the remainder of this Agreement.

14.11 Waiver. A waiver by either party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future.

14.12 Headings. Headings in this Agreement are included for ease of reference only and have no legal effect.

14.13 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

14.14 Drafting. This Agreement was negotiated at arm's-length and entered into freely by the parties and upon the advice of their respective counsel. All parties hereto are to be deemed the drafters of this Agreement. No provision hereof shall be construed in favor of or against any party hereto based upon principles of *contra proferentem* or any other presumption as to inequality of bargaining power or otherwise.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed in their respective names and on their behalf, as of the date first above written.

ASCENDIS

By: /s/ Jan Møller Mikkelsen

Title: CEO

Date: 06-Feb-2020

By: /s/ Michael Wolff Jensen

Title: Chief Legal Officer

06-Feb-2020

SHARP CORPORATION

By: /s/ Jeff Benedict

Title: Chief Commercial Officer

Date: Feb 5 2020

EXHIBIT A

PRODUCTS / PRICES

[***]

Ascendis agrees to an annual revenue minimum of $**[***]** for packaged kits **[***]**

EXHIBIT A-1

SERIALIZATION PRICES AND

TERMS AND CONDITIONS

Omitted pursuant to Regulation S-K, Item 601(a)(5)

EXHIBIT B

SPECIFICATIONS

Omitted pursuant to Regulation S-K, Item 601(a)(5)

EXHIBIT C

INITIAL FORECAST

Omitted pursuant to Regulation S-K, Item 601(a)(5)

EXHIBIT D

QUALITY AGREEMENT

Omitted pursuant to Regulation S-K, Item 601(a)(5)

EXHIBIT E

TERRITORY

Omitted pursuant to Regulation S-K, Item 601(a)(5)

EXHIBIT F

ASCENDIS SPECIFIC EQUIPMENT

Omitted pursuant to Regulation S-K, Item 601(a)(5)

Exhibit 8.1

Ascendis Pharma A/S

Subsidiaries of the Registrant

Name	Jurisdiction of Incorporation
Ascendis Pharma GmbH	Germany
Ascendis Pharma, Inc.	Delaware, USA
Ascendis Pharma, Endocrinology Division A/S	Denmark
Ascendis Pharma, Ophthalmology Division A/S	Denmark
Ascendis Pharma Bone Diseases A/S	Denmark
Ascendis Pharma Growth Disorders A/S	Denmark
Ascendis Pharma Oncology Division A/S	Denmark

Exhibit 12.1

CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jan Møller Mikkelsen, certify that:

1. I have reviewed this annual report on Form 20-F of Ascendis Pharma A/S (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a 15(f) and 15d 15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: April 2, 2020

By: /s/ Jan Møller Mikkelsen
Name: Jan Møller Mikkelsen
Title: Chief Executive Officer

Exhibit 12.2

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott T. Smith, certify that:

1. I have reviewed this annual report on Form 20-F of Ascendis Pharma A/S (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a 15(f) and 15d 15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: April 2, 2020

By: /s/ Scott T. Smith
Name: Scott T. Smith
Title: Chief Financial Officer and Principal Financial Officer

Exhibit 13.1

CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002*

In connection with the Annual Report on Form 20-F of Ascendis Pharma A/S (the "Company") for the year ended December 31, 2019, as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Jan Møller Mikkelsen, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 2, 2020

By: /s/ Jan Møller Mikkelsen
Name: Jan Møller Mikkelsen
Title: Chief Executive Officer

Exhibit 13.2

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002*

In connection with the Annual Report on Form 20-F of Ascendis Pharma A/S (the "Company") for the year ended December 31, 2019, as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Scott T. Smith, as Chief Financial Officer and Principal Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 2, 2020

By: /s/ Scott T. Smith
Name: Scott T. Smith
Title: Chief Financial Officer and Principal Financial Officer

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-203040, 333-210810, 333-211512, 333-213412, 333-214843, 333-216883 and 333-228576 on Form S-8 and Registration Nos. 333-209336, 333-211511, 333-216882, 333-223134 and 333-225284 on Form F-3 of our reports dated April 2, 2020, relating to the consolidated financial statements of Ascendis Pharma A/S and subsidiaries (the "Company") (which report expresses an unqualified opinion and includes an explanatory paragraph regarding the Company's change in its method of accounting for leases from January 1, 2019 due to the adoption of International Financial Reporting Standard 16 Leases), and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 20-F of Ascendis Pharma A/S for the year ended December 31, 2019.

Deloitte Statsautoriseret Revisionspartnerselskab
CVR no. 33963556

/s/ Sumit Sudan
State Authorised Public Accountant

/s/ Lars Hansen
State Authorised Public Accountant

Copenhagen, Denmark

April 2, 2020