

As confidentially submitted to the Securities and Exchange Commission on August 1, 2014. This draft registration statement has not been filed publicly with the Securities and Exchange Commission and all information contained herein remains confidential.

Registration No. 333-

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

**FORM F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

Ascendis Pharma A/S

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

The Kingdom of Denmark
(State or other jurisdiction of incorporation or organization)

2834
(Primary Standard Industrial Classification Code Number)

NOT APPLICABLE
(I.R.S. Employer Identification Number)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price ⁽¹⁾	Amount of registration fee ⁽²⁾
Ordinary shares, DKK 1 nominal value per share	\$	\$

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes shares that the underwriters have the option to subscribe for to cover overallotments, if any.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any U.S. state or other jurisdiction where the offer or sale is not permitted.

Subject to completion, dated _____, 2014
PROSPECTUS

Shares



ASCENDIS PHARMA A/S

Ordinary Shares

This is the initial public offering of ordinary shares of Ascendis Pharma A/S. We are offering _____ of our ordinary shares.

No public market currently exists for our ordinary shares. We anticipate that the initial public offering price will be between \$ _____ and \$ _____ per share.

We intend to apply to list our common stock on The NASDAQ Global Market under the symbol “_____.”

We are an “emerging growth company” as defined by the Jumpstart Our Business Startups Act of 2012, and as such, will be subject to reduced public company reporting requirements for this prospectus and future filings.

Investing in our ordinary shares involves risks. See “[Risk Factors](#)” beginning on page 11 of this prospectus.

	<u>Per Share</u>	<u>Total</u>
Price to the public	\$ _____	\$ _____
Underwriting commissions ⁽¹⁾	\$ _____	\$ _____
Proceeds to us (before expenses)	\$ _____	\$ _____

(1) We refer you to “Underwriting” for additional disclosure regarding underwriter compensation.

We have granted the underwriters a 30-day option to subscribe for up to _____ additional ordinary shares on the same terms and conditions set forth above if the underwriters sell more than _____ ordinary shares in this offering.

Neither the Securities and Exchange Commission, any U.S. state securities commission, the Danish Financial Supervisory Authority, nor any other foreign securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the ordinary shares on or about _____, 2014.

, 2014

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Neither we nor the underwriters have authorized anyone to provide you with information that is different from that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell ordinary shares and seeking offers to subscribe for ordinary shares only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front of this prospectus, regardless of the time of delivery of this prospectus or any sale of ordinary shares.

Until _____, 2014 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside of the United States: Neither we nor any of the underwriters have taken any action to permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

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Ascendis is a trademark of ours that we use in this prospectus. This prospectus also includes trademarks, tradenames, and service marks that are the property of other organizations. Solely for convenience, our trademark and tradenames referred to in this prospectus appear without the ® and ™ symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to our trademark and tradenames.

PRESENTATION OF FINANCIAL INFORMATION

We maintain our books and records in euros and report under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. None of the consolidated financial statements in this prospectus were prepared in accordance with generally accepted accounting principles in the United States.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our ordinary shares, you should read this entire prospectus carefully, including the sections of this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements contained elsewhere in this prospectus. Unless the context otherwise requires, references in this prospectus to the “company,” “Ascendis Pharma,” “we,” “us” and “our” refer to Ascendis Pharma A/S and its subsidiaries. In this prospectus, references to “DKK” are to Danish kroner, the lawful currency of the Kingdom of Denmark and references to “EUR” and “€” are to euros, the official currency of the European Central Bank.

Overview

We are applying our TransCon technology to develop a pipeline of long-acting prodrug therapies with best-in-class profiles that address large markets with significant unmet medical needs. Our TransCon technology establishes a new paradigm that combines the benefits of conventional prodrug and sustained release technologies, and is broadly applicable to proteins, peptides and small molecules. TransCon prodrugs predictably release unmodified active parent drugs and may offer advantages that include superior efficacy, safety, tolerability and compliance, including less frequent dosing and the ability to switch patients to subcutaneous injections from burdensome continuous infusions and less frequent dosing. We can design TransCon prodrugs to act systemically or locally in areas that are difficult to treat with conventional therapies. By primarily focusing on biological targets that have been clinically validated, we can leverage available knowledge regarding a target’s activity. Based on this selective approach, we know what drug levels must be maintained in the body for optimal efficacy and safety, and we can design the release half-life of our TransCon prodrugs to maintain these levels to achieve the desired pharmacological effect. We move a product candidate into development after it demonstrates a superior profile in animal models that we believe correlate to human clinical experience. This strategy is designed to reduce risk and increase productivity.

We are developing our most advanced and wholly-owned product candidate, TransCon human Growth Hormone, or TransCon hGH, for the treatment of growth hormone deficiency, or GHD. We have successfully completed a Phase 2 study of TransCon hGH in adults with GHD, and are currently enrolling children with GHD in a six-month Phase 2 pediatric study. In October 2014, we expect to report three-month data, including height velocity, from 50% of the patients in our Phase 2 pediatric study, and top-line data for all patients in the trial in the first half of 2015. In addition, the U.S. Food and Drug Administration, or the FDA, has accepted an Investigational New Drug application, or an IND, for TransCon Treprostinil, our product candidate for the treatment of pulmonary arterial hypertension, or PAH.

We believe that our TransCon technology has been further validated by our multi-product collaborations with market-leading biopharmaceutical companies, Sanofi and Genentech. As of June 30, 2014, we have received approximately €65 million of non-dilutive financing from collaboration partners, and we are eligible to receive up to an additional aggregate of €220 million in development and regulatory milestone payments for products currently being developed under our collaboration agreements, as well as sales-based milestone payments and royalties on future net sales of products. We hold worldwide rights to our TransCon technology and have no third-party payment obligations with respect to our TransCon technology or any of our product candidates. All of our TransCon prodrugs are new molecular entities and should therefore be eligible to be granted new intellectual property rights, including new composition of matter patents.

Our TransCon Technology

Our TransCon technology enables us to create long-acting prodrug therapies with potentially significant advantages over existing marketed drug products. A prodrug is an inactive, or significantly less active, form of a

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parent drug that is designed to be activated only after it undergoes transformation in the body. Conventional prodrug technologies rely on transformation by processes that cannot be controlled to facilitate both predictable and sustained release of the parent drug.

Our TransCon technology is differentiated in that it enables us to design long-acting prodrugs that predictably release an unmodified active parent drug at predetermined rates governed only by physiological pH and temperature conditions. Because these conditions are tightly regulated in the body, we are able to design our TransCon prodrugs to predictably release an unmodified active parent drug over an extended period of time. In addition to retaining the original mode of action of the parent drug, TransCon prodrugs may offer advantages that include less frequent dosing, less burdensome administration, and improved efficacy, safety and tolerability profiles.

Our Proprietary Product Candidates

TransCon human Growth Hormone

Our most advanced product candidate is TransCon hGH for the treatment of 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 premature mortality, increased adiposity, or fat mass, as well as neuropsychiatric-cognitive, cardiovascular, neuromuscular, metabolic and skeletal abnormalities. According to MedTRACK, global sales from currently marketed hGH products grew to over \$3 billion in 2013. The current standard of care for the treatment of GHD requires patients to receive daily injections over many years. The administrative burden of daily injections often results in poor patient compliance and can lead to suboptimal treatment outcomes. To address these unmet medical needs, we are developing TransCon hGH for once-weekly administration. Because TransCon hGH is a prodrug that releases unmodified growth hormone, TransCon hGH maintains the same mode of action as currently prescribed daily hGH therapies. Our clinical studies of TransCon hGH have demonstrated a comparable efficacy, safety, tolerability and immunogenic profile to that of daily growth hormone. If approved, TransCon hGH may reduce the burden of daily treatment by requiring significantly fewer injections, which may improve patient compliance and treatment outcomes. We have successfully completed a Phase 2 study of TransCon hGH in adults with GHD and are currently enrolling children with GHD in a Phase 2 pediatric study. In October 2014, we expect to report three-month data, including height velocity, from 50% of the patients in our Phase 2 pediatric study, and top-line data for all patients in the trial in the first half of 2015.

TransCon Treprostinil

We are developing TransCon Treprostinil for the treatment of PAH, a life-threatening disease characterized by elevated blood pressure in the pulmonary arteries. According to MedTRACK, the worldwide market for PAH treatment exceeded \$4 billion in 2013. Treprostinil, the active agent in Remodulin® developed by United Therapeutics Corporation, or United Therapeutics, belongs to a class of drugs known as prostacyclins, and is the leading infused therapy for the treatment of PAH. TransCon Treprostinil is designed as a once-daily self-administered subcutaneous injection, offering the same efficacy as continuously infused prostacyclins with a safer and improved tolerability profile. TransCon Treprostinil is expected to offer significant advantages as compared to current infused prostacyclin therapy, including minimizing infusion site pain and the risk of bloodstream infection. In September 2012, we entered into a collaboration agreement with United Therapeutics for the development and commercialization of TransCon Treprostinil. In May 2014, United Therapeutics filed an IND for TransCon Treprostinil, which was subsequently accepted by the FDA in June 2014. On June 30, 2014, we received a notice from United Therapeutics informing us of its intent to terminate the collaboration agreement for convenience, and we are in the process of negotiating the transition of the program back to us.

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TransCon Osteoarthritis pipeline

We are applying our TransCon technology to a series of active parent drugs to assess their ability to be administered intra-articularly on an up to half-yearly basis and to provide long-term pain reduction and modify disease.

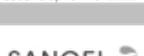
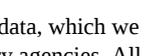
Our Collaborations

In addition to our proprietary programs, we have formed multi-product collaborations with leading biopharmaceutical companies on market-leading products and in therapeutic categories that are of strategic importance to our collaboration partners. These collaborations are as follows:

- Sanofi: TransCon Insulin in diabetes; and
- Genentech: TransCon Ranibizumab in wet age-related macular degeneration, or AMD, and other ophthalmic indications.

We entered into a collaboration with Sanofi to develop TransCon Insulin as a once-weekly diabetes therapy, and with Genentech to develop TransCon Ranibizumab, to support up to half-yearly intravitreal injections, or injections into the back of the eye, for the treatment of ophthalmic diseases such as wet AMD.

TransCon Product Candidate Pipeline

Product Candidate	Primary Indication	Approved Parent Drug	Stage of Development	Market Size	Worldwide Commercial Rights
TransCon Human Growth Hormone	Pediatric Growth hormone deficiency	ü	Phase 2 (Interim data expected: Oct 2014/ Top-Line data expected H1 2015)	> \$3 billion	
	Adult Growth hormone deficiency	ü	Phase 2 completed		
TransCon Treprostinil	Pulmonary Arterial Hypertension	ü	Accepted IND	> \$1 billion	
TransCon Steroid	Osteoarthritis (intra-articular administration)	ü	Preclinical	> \$1 billion	
TransCon Candidate(s)		ü	Preclinical		
TransCon Insulin	Diabetes	ü	Preclinical safety completed	>\$7 billion	
TransCon Peptide			Preclinical	n/a	
TransCon Ranibizumab	Ophthalmology	ü	Preclinical	> \$5 billion	

When we apply our TransCon technology to already approved drug compounds, we may benefit from established clinical safety and efficacy data, which we believe reduces drug development risk and may allow us to utilize expedited approval pathways provided by the FDA and European regulatory agencies. All of our TransCon prodrugs are new molecular entities and should therefore be eligible to be granted new intellectual property rights, including new composition of matter patents.

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We maintain an intellectual property portfolio composed of approximately 30 issued patents and approximately 160 patent applications as of June 30, 2014, with claims directed to composition of matter, process, formulation and/or methods-of-use for our product candidates and core TransCon technology. In addition, each of our collaboration partners has granted us rights that enable us to freely commercialize all improvements to the TransCon technology developed by our collaboration partners outside of the field identified in their respective collaboration agreements.

Our Strategy

Our goal is to leverage our TransCon technology to create a pipeline of proprietary products and form collaborations with market-leading biopharmaceutical companies to develop new products that incorporate our TransCon technology in therapeutic areas that are of strategic importance to our collaboration partners. Key elements of our strategy to achieve this goal include:

- rapidly advance the development of our advanced product candidates, including our product candidates, TransCon hGH and TransCon Treprostinil;
- leverage our TransCon technology to create a pipeline of new product candidates with best-in-class therapeutic profiles;
- continue to establish strategic collaborations with market-leading biopharmaceutical companies;
- pursue expedited regulatory pathways for approval and commercialization of our product candidates; and
- strengthen our leadership position in the field of long-acting prodrug technology through investments in our technology, manufacturing capabilities and know-how.

Our Senior Management Team

We are led by a team of experienced biopharmaceutical industry executives with substantial experience in the development and approval of innovative therapies. Our senior management team is led by our co-founder and Chief Executive Officer, Jan Møller Mikkelsen. Most recently Mr. Mikkelsen was the President and CEO of LifeCycle Pharma A/S, now known as Veloxis Pharmaceuticals A/S, which develops pharmaceutical solutions to prevent organ rejection in kidney transplant patients as well as lipid management products. Prior to Veloxis Pharmaceuticals A/S, Mr. Mikkelsen co-founded Profound Pharma A/S, which was successfully acquired by Maxygen, Inc. in 2000. At Maxygen, Mr. Mikkelsen was appointed President of the Pharmaceutical Division, where he managed 100 employees out of both Denmark and the United States. Our scientific team is led by Harald Rau, Ph.D., who manages our scientific operations and heads our research group. Before joining Ascendis, Dr. Rau co-founded Complex Biosystems, which was later acquired by Ascendis. At Complex Biosystems, Dr. Rau headed the company's R&D division and led the development and maturation of the TransCon Linker Technology, a key Ascendis technology. Other members of our senior management team have discovered or developed important products and product candidates in the protein discovery field, in key roles in leading biopharmaceutical companies such as ACADIA Pharmaceuticals A/S, Genmab A/S, Veloxis Pharmaceuticals A/S, Maxygen, Inc., Novo Nordisk A/S, Transcept Pharmaceuticals, Inc. and United Therapeutics.

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Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this prospectus immediately following this prospectus summary. These risks include the following:

- we have a limited operating history, no products approved for commercial sale and we may incur significant losses in the future;
- we have never generated any revenue from product sales and may not be able to sustain our limited profitability;
- we may require substantial additional financing;
- we are substantially dependent on the success of our lead product candidates, which may not be successful in preclinical studies or clinical trials, receive regulatory approval or be successfully commercialized;
- we depend on collaboration partners to develop and conduct clinical studies with, obtain regulatory approvals for, and manufacture, market and sell our collaboration product candidates;
- clinical drug development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays in our clinical studies;
- our product candidates may never achieve market acceptance or commercial success;
- our proprietary TransCon technology is a new approach to drug development and may not result in any product of commercial value; and
- our intellectual property may not be adequate to enable us to compete effectively in our market, and we may become subject to claims alleging infringement of third parties’ intellectual property rights.

Corporate Information

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) in December 2007. We commenced operations in December 2007 in connection with the acquisition of the company that invented our TransCon technology, Complex Biosystems GmbH. Our principal executive offices are located at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark and our telephone number is +45 36 94 44 86. Our website address is www.ascendispharma.com. The information on, or that can be accessed through, our website is not part of and should not be incorporated by reference into this prospectus. We have included our website address as an inactive textual reference only.

Implications of Being an Emerging Growth Company

As a company with less than \$1 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- a requirement to have only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations disclosure; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

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We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than \$1 billion in annual revenue, have more than \$700 million in market value of the ordinary shares held by non-affiliates, or issue more than \$1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens, and therefore the information that we provide shareholders may be different than the information you might receive from other public companies in which you hold equity.

The JOBS Act permits an emerging growth company like us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to “opt out” of this provision and, as a result, we will adopt new or revised accounting standards as required for public companies. This decision to opt out of the extended transition period is irrevocable.

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THE OFFERING

Ordinary shares offered by us	shares
Ordinary shares to be outstanding after this offering	shares
Option to subscribe for additional ordinary shares to cover over-allotments, if any	We have granted the underwriters an option, exercisable within 30 days from the date of this prospectus, to subscribe for up to additional ordinary shares.
Use of Proceeds	We estimate that the net proceeds from this offering will be approximately \$ million, or approximately \$ million if the underwriters exercise their option to subscribe for additional ordinary shares in full after deducting the underwriting commissions and estimated offering expenses payable by us, based on an assumed initial public offering price of \$ per ordinary share, the midpoint of the price range set forth on the cover page of this prospectus. We expect to use the net proceeds from this offering to fund the continued development of our proprietary TransCon product candidates, including the completion of our Phase 2 pediatric study of TransCon hGH, preparing to conduct a Phase 3 study of TransCon hGH, to further develop our TransCon Treprostinil and TransCon Osteoarthritis programs, to develop product candidates in new therapeutic areas, to strengthen our TransCon technology and for working capital and general corporate purposes. See “Use of Proceeds” for a more complete description of the intended use of proceeds from this offering.
Risk Factors	See “Risk Factors” and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our ordinary shares.
Proposed symbol on The NASDAQ Global Market	“ ”

The number of ordinary shares to be outstanding after this offering is based on 2,700,487 ordinary shares outstanding as of June 30, 2014, and excludes the following:

- 312,452 ordinary shares issuable upon exercise of outstanding warrants with an expiration date of August 21, 2015 at a weighted average exercise price of €12.7154 per share (\$17.3471);
- 300,773 ordinary shares issuable upon exercise of outstanding warrants with an expiration date of August 21, 2023 at a weighted average exercise price of €31.9847 per share (\$43.6353); and
- 521 ordinary shares issuable upon exercise of warrants pursuant to future warrant grants.

Unless otherwise indicated, the number of ordinary shares described assumes the following:

- a -for- split of our share capital to be effected prior to the effectiveness of the registration statement of which this prospectus is a part;

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- the conversion of all of our outstanding ordinary A, preference B and preference C shares into an aggregate of 2,700,487 ordinary shares in connection with the closing of this offering;
- the filing, registration and effectiveness of our amended and restated articles of association, which will occur in connection with the closing of this offering;
- no exercise of outstanding warrants or issuance of ordinary shares upon such exercise; and
- no exercise of the underwriters' option to subscribe for additional ordinary shares to cover over-allotments.

We refer to our preference B shares and preference C shares collectively as “preference shares” in this prospectus, as well as for financial reporting purposes and in the financial tables included in this prospectus, as more fully explained in Note 11 to our audited consolidated financial statements.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables present summary consolidated financial data for our business. We derived the summary consolidated statement of profit or loss and other comprehensive income data for the years ended December 31, 2013 and 2012 and the summary consolidated statement of financial position data on an actual basis as of December 31, 2013 from our audited consolidated financial statements included elsewhere in this prospectus. We maintain our books and records in euros, and prepare our consolidated financial statements in accordance with IFRS as issued by the IASB. The pro forma and pro forma as adjusted data included in the summary consolidated statement of financial position data is unaudited. You should read this data together with our audited consolidated financial statements and related notes appearing elsewhere in this prospectus and the information under the captions “Capitalization”, “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results are not necessarily indicative of our future results.

Summary Consolidated Statement of Profit or Loss and Other Comprehensive Income Data:

	Year Ended December 31,	
	2013⁽¹⁾	2012
	(EUR'000, except share and per share data)	
Revenue	20,408	15,583
Research and development costs	(12,713)	(11,380)
General and administrative expenses	(2,416)	(2,690)
Operating profit	5,279	1,513
Finance income	158	4
Finance expenses	(732)	(232)
Profit before tax	4,705	1,285
Tax on profit for the year	(626)	(35)
Net profit for the year	4,079	1,250
Other comprehensive income		
<i>Items that may be reclassified subsequently to profit or loss:</i>		
Exchange differences on translating foreign operations	(6)	(51)
Other comprehensive loss for the year, net of tax	(6)	(51)
Total comprehensive income for the year, net of tax	4,073	1,199
Profit for the year attributable to owners of the Company	4,079	1,250
Total comprehensive income for the year attributable to owners of the Company	4,073	1,199
	EUR	EUR
Basic and diluted earnings per share, preference C shares ⁽²⁾	1.94	0.57
Basic and diluted earnings per share, preference B shares ⁽²⁾	—	—
Basic and diluted earnings per share, ordinary shares ⁽²⁾	—	—

(1) The year ended December 31, 2013 has been restated for the correction of an error. See Note 1 to our consolidated financial statements for more information.

(2) For additional information regarding our basic and diluted earnings per share, see our Consolidated Statements of Profit or Loss and Other Comprehensive Income included in our consolidated financial statements.

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Summary Consolidated Statement of Financial Position Data:

The table below presents summary consolidated statement of financial position data as of December 31, 2013:

- on an actual basis;
- on a pro forma basis to give effect to:
 - the conversion of all of our outstanding ordinary A, preference B and preference C shares into an aggregate of 2,700,487 ordinary shares in connection with the closing of this offering;
 - the filing, registration and effectiveness of our amended and restated articles of association, which will occur in connection with the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to the sale of ordinary shares in this offering at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting commissions and estimated offering expenses payable by us.

	As of December 31, 2013	
	Actual ⁽¹⁾	Pro Forma As Adjusted ⁽²⁾ (unaudited)
	(EUR'000)	
Cash and cash equivalents	19,430	
Total assets	26,700	
Retained earnings	3,220	
Total equity	6,301	

(1) The year ended December 31, 2013 has been restated for the correction of an error. See Note 1 to our consolidated financial statements for more information.

(2) Each \$1.00 (€) increase or decrease in the assumed initial public offering price of \$ per ordinary share (€), which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, respectively, the amount of cash and cash equivalents, working capital, total assets and total equity by \$ million (€ million), assuming the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares we are offering. An increase or decrease of 1,000,000 in the number of ordinary shares we are offering would increase or decrease, respectively, the amount of cash and cash equivalents, working capital, total assets and shareholders' equity by approximately \$ million (€ million), assuming the assumed initial public offering price per ordinary share, as set forth on the cover page of this prospectus, remains the same. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

RISK FACTORS

Investing in our ordinary shares involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our ordinary shares. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our ordinary shares could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

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 TransCon technology to develop long-acting prodrug therapies with several product candidates in clinical and preclinical development. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused substantially all of our efforts on our research and development activities and, in particular, developing our proprietary TransCon technology. We have only a limited operating history upon which you 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. Our net profit for the years ended December 31, 2013 and 2012 was approximately €4.1 million and €1.3 million, respectively. As of December 31, 2013 and 2012, we had retained earnings of €3.2 million and accumulated deficit of €0.9 million, respectively. The net profit we have experienced in recent years is not indicative of our future results.

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

Even if we receive the potential milestone payments or royalty payments from our 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 cannot be certain that we will not incur significant losses in the future. Possible future losses will 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 and may not be able to sustain our limited profitability.

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

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

In cases where we, or our collaboration partners, are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which regulatory approval is granted, the accepted price for the product, the ability to get reimbursement for our products at any price and the extent of our royalty rights for that territory. If the number of patients suitable for our product candidates is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, 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. A decline in the value of our ordinary shares could cause you to lose all or part of your investment.

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

Since our inception, most of our resources have been dedicated to our research and development activities and, in particular, developing our proprietary TransCon technology and lead product candidates. As of December 31, 2013, we had cash and cash equivalents of €19.4 million. We believe that we will continue to expend substantial

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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 capital resources, together with the net proceeds from this offering, will allow us to fund our operating plan through at least the 12 months from the date of this prospectus. 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 that have not been licensed, including the ability to enroll patients in a timely manner for clinical trials;
- the time and cost necessary to obtain regulatory approvals for our product candidates that have not been licensed and the costs of post-marketing studies that could be required by regulatory authorities;
- our progress and the progress of our collaboration partners in the successful commercialization and co-promotion of our lead product candidates and our efforts to develop and commercialize our other existing product candidates;
- the manufacturing, selling and marketing costs associated with product candidates, including the cost and timing of building our sales and marketing capabilities;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the sales price and the availability of adequate third-party coverage and reimbursement for our product candidates;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the number and scope of preclinical and discovery programs that we decide to pursue or initiate;
- the potential acquisition and in-licensing of other technologies, products or assets;
- the time and cost necessary to respond to technological and market developments; and
- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation, including costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of our product candidates.

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

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Our cash position and our need for additional sources of capital to fund our ongoing operations have raised substantial doubt regarding our ability to continue as a going concern.

Our cash position of approximately €19.4 million as of December 31, 2013, and our projected cash inflow from operating activities during 2014, will not be sufficient to meet our obligations, support operations and fully execute our strategic plan through December 31, 2014. Accordingly, we have expressed substantial doubt regarding our ability to continue as a going concern in our consolidated financial statements included in this prospectus and our independent registered public accounting firm has included an explanatory paragraph in its report on our consolidated financial statements as of, and for the year ended, December 31, 2013 with respect to this uncertainty. Our ability to continue as a going concern will require us to obtain additional financing to fund our operations or generate sufficient revenue from our operations. There is no assurance that additional capital will be available when needed on acceptable terms, or at all, or that it will be available in amounts that will allow us to continue as a going concern. Meaningful revenue will likely not be available until, and unless, we are able to enter into a new strategic collaboration with substantial up-front payments, or until our product candidates are approved by the FDA, the EMA or comparable regulatory authorities and successfully commercialized. Our failure to obtain sufficient funds on acceptable terms when needed could harm our business, results of operations and financial condition. Future reports on our consolidated financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. The perception that we may not be able to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by our current and future investors, collaboration partners, suppliers and employees. If we are unable to continue as a going concern, you could lose all or part of your investment in our company.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Such financing may result in dilution to shareholders, 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 lead product candidates, which may not be successful in preclinical 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 lead product candidates utilizing our proprietary TransCon technology. In particular, we are currently conducting a Phase 2 pediatric trial for TransCon hGH. In addition, in June 2014 the FDA accepted an IND for TransCon Treprostinil, which was initially filed by our former collaboration partner, United Therapeutics. 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 lead product candidates, if approved. The clinical and commercial success of our lead product candidates and our TransCon technology will depend on a number of factors, including the following:

- the timely completion of the ongoing clinical trial of TransCon hGH, which will depend substantially upon the satisfactory performance of third-party contractors, and the initiation of the Phase 1 study of TransCon Treprostinil;

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- our ability and that of our collaboration partners to establish commercial-scale manufacturing processes for our lead product candidates, which has not yet been demonstrated;
- whether our lead 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 lead product candidates;
- the prevalence and severity of adverse side effects of our lead product candidates;
- the timely receipt of necessary marketing approvals from the EMA, the FDA and similar regulatory authorities;
- our ability and that of our collaboration partners to successfully commercialize our lead 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 lead product candidates as safe and effective by patients and the medical community;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- obtaining and sustaining an adequate level of coverage and reimbursement for our lead product candidates by third-party payors;
- the effectiveness of our collaboration partners' marketing, sales and distribution strategies and operations;
- our ability and that of our collaboration partners, or any third-party manufacturer we or our collaborators contract with, to manufacture supplies of our lead 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 lead 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 lead product candidates following approval, if approved.

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

Additionally, our clinical and regulatory approval plan for TransCon hGH is to conduct a single Phase 3 trial in a pediatric population with a primary endpoint of mean height velocity measured over 12 months. It is possible, however, that because TransCon hGH is a prodrug form of hGH that it is a new molecular entity, we will not be able to use this clinical and regulatory approval strategy. If we have to conduct additional or different trials, this could increase the amount of time and expense required for regulatory approval of TransCon hGH, if approved at all. We plan to report three month mean height velocity data in 50% of our patients in October 2014. If the three and six month mean height velocities that we observe for TransCon hGH in the on-going Phase 2 pediatric trial do not correlate to twelve month mean height velocities that we ultimately observe in any Phase 3 clinical trials that we may conduct, TransCon hGH may not achieve the required primary endpoint in the Phase 3 clinical trial, and therefore may not receive regulatory approval.

Accordingly, we cannot be certain that our lead product candidates will ever be successfully commercialized or that we will ever generate revenue from sales of such product candidates. If we and our collaboration partners are

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not successful in completing the development of, obtaining approval for, and commercializing our lead 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 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. For example, there can be no assurance that our ongoing Phase 2 clinical trial will meet its primary or secondary endpoints or not show any negative safety risks. The results of preclinical and clinical studies of our product candidates may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in preclinical and clinical studies for TransCon hGH do not ensure that the ongoing Phase 2 clinical trial, or future clinical trials, will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates or to be able to use an expedited regulatory pathway for approval of our product candidates.

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

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

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

We could also encounter delays if a clinical trial is suspended or terminated by us, our collaboration partner for a product candidate, by the Ethics Committee or IRBs of the institutions in which such trials are being conducted, by an independent data safety monitoring board, or DSMB, for such trial or by European Economic Area, or

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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 our on-going Phase 2 pediatric study of TransCon hGH in Europe and North Africa and conducting clinical trials in foreign countries presents additional risks that may delay completion of clinical trials. These risks include the failure of physicians or enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. In addition, the EMA or the FDA may determine that the clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product candidate when administered in EEA or U.S. patients, and are thus not supportive of an application for a marketing authorization in the EEA or of an NDA approval in the United States. As a result, the EMA or the FDA may not accept data from clinical trials conducted outside the EEA or the United States, respectively, and may require that we conduct additional clinical trials or obtain additional data before we can proceed with filing an NDA in the United States or a marketing authorization application in the EEA. The EMA or the FDA may even require conducting additional clinical trials in the EEA or the United States, respectively.

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

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

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

If our collaboration partners do not perform in the manner we expect or fulfill their responsibilities in a timely manner, or at all, if our agreements with them terminate or if the quality or accuracy of the clinical data they

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obtain is compromised, the clinical development, regulatory approval and commercialization efforts related to our collaboration product candidates could be delayed or terminated and it could become necessary for us to assume the responsibility at our own expense for the clinical development of such product candidates. In that event, we would likely be required to limit the size and scope of efforts for the development and commercialization of such product candidate, to seek additional financing to fund further development, or to identify alternative strategic collaboration partners, and our potential to generate future revenue from royalties and milestone payments from such product candidate would be significantly reduced or delayed and our business would be harmed. For example, in September 2012, we entered into a collaboration agreement with United Therapeutics for the development and commercialization of TransCon Treprostinil. In May 2014, United Therapeutics filed an IND for TransCon Treprostinil, which was subsequently accepted by the FDA in June 2014. On June 30, 2014, we received a notice from United Therapeutics informing us of its intent to terminate the collaboration agreement for convenience, and we are in the process of transitioning the program back to us.

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

- our collaboration partners have the unilateral ability to choose not to develop a collaboration product for one or more indications for which such product has been or is currently being evaluated, and our collaboration partners may choose to pursue an indication that is not in our strategic best interest or to forego an indication that they believe does not provide significant market potential even if clinical data is supportive of further development for such indication;
- our collaboration partners may choose not to develop and commercialize our collaboration products in certain relevant markets;
- our collaboration partners may take considerably more time advancing our product candidates through the clinical and regulatory process than we currently anticipate, which could materially delay the achievement of milestones and, consequently the receipt of milestone payments from our collaboration partners;
- our collaboration partners have substantial discretion under their respective agreements regarding how they structure their efforts and allocate resources to fulfill their obligations to diligently develop, manufacture, obtain regulatory approval for and commercialize our collaboration products;
- our collaboration partners control all aspects of commercialization efforts under their respective license agreements and may change the focus of their development and commercialization efforts or pursue higher-priority programs and, accordingly, reduce the efforts and resources allocated to their collaborations with us;
- our collaboration partners are solely responsible for obtaining and maintaining all regulatory approvals and may fail to develop a commercially viable formulation or manufacturing process for our product candidates, and may fail to manufacture or supply sufficient drug substance for commercial use, if approved, which could result in lost revenue;
- our collaboration partners may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- if any of our agreements with our collaboration partners terminate, we will no longer have any rights to receive potential revenue under such agreement, in which case we would need to identify alternative means to continue the development, manufacture and commercialization of the affected product candidates, alone or with others;
- our collaboration partners have the discretion to sublicense their rights with respect to our collaboration technology in connection with collaboration product candidates to one or more third parties without our consent;

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- 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; for example, United Therapeutics sent us a notice of termination of our collaboration agreement and has stated that the termination of the program was a result of business reasons, including the approval of their drug, Orenitram™; and
- if our collaboration partners receive approval for any of the collaboration product candidates, reductions in marketing or sales efforts or a discontinuation of marketing or sales of our product candidates by our collaboration partners would reduce any royalties we could be entitled to receive, which are based on the sales of our product candidates by our collaboration partners.

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

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

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

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

We may form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to our independent programs that we believe will complement or augment our existing business. We have historically engaged, and intend to continue to engage, in partnering discussions with a range of biopharmaceutical companies and could enter into new collaborations at any time. We face significant competition in seeking appropriate strategic partners, and the negotiation process to secure appropriate terms is time-consuming and complex. Any delays in identifying suitable development partners and entering into agreements to develop our product candidates could also delay the commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. Moreover, we may not be successful in our efforts to establish such a strategic partnership for any future product candidates and programs on terms that are acceptable to us, or at all. This may be for a number of reasons, including that our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, and/or third parties may not view our product candidates

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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, are at an early stage of development and we may not be successful in our efforts to successfully develop these products or expand our pipeline of product candidates.

A key element of our strategy is to expand our pipeline of product candidates utilizing our proprietary TransCon technology, and to advance such product candidates through clinical development, either on our own or in conjunction with strategic collaboration partners. Other than TransCon hGH and TransCon Trepstinil, our current unlicensed product candidates, including TransCon candidates in our osteoarthritis program, are in discovery and the lead identification stages of preclinical development, and will require substantial preclinical and clinical development and testing, and eventually regulatory approval, prior to commercialization. TransCon hGH is our only unlicensed product candidate currently in clinical trials and, although the FDA accepted an IND for TransCon Trepstinil in June 2014, we have not yet commenced clinical trials for this product candidate. On June 30, 2014, we received a notice from United Therapeutics terminating the collaboration agreement for convenience, and we are in the process of transitioning the program back to us. Our other unlicensed product candidates are in preclinical development and may require significant time and additional research and development before we can file a Clinical Trial Application or IND with regulatory authorities to begin clinical studies. Of the large number of drugs in development, only a small percentage of such drugs successfully complete the EMA or FDA regulatory approval process and are commercialized. Accordingly, even if we are able to continue to fund such development programs, our product candidates may not be advanced to clinical studies or be successfully developed or commercialized. In addition, our preclinical product candidates may not demonstrate the advantages we expect from application of our TransCon technology in preclinical studies. In such event, we may decide not to progress any such product candidates into clinical trials.

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

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

Even if we are successful in continuing to expand our pipeline, through our own research and development efforts or by pursuing in-licensing or acquisition of product candidates, the potential product candidates that we

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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.

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

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

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

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

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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 lead product candidates for which marketing approval is obtained will depend on a number of factors, including:

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

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

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 our 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. For example, in a Phase 2 study evaluating 37 adult patients treated with TransCon hGH, adverse events included fatigue (seven patients) and headache (seven patients), which were considered certainly, probably, or possibly drug-related. 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 these or other side effects, such trials could be suspended or terminated and the EMA, the FDA or similar regulatory authorities could order our collaboration partners or us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- regulatory authorities may withdraw their approval of the product or seize the product;

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

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

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

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

We are aware of several pharmaceutical and biopharmaceutical companies that have commenced clinical studies of products or have successfully commercialized products addressing areas that we are targeting. For example, several companies are developing long-acting products for the treatment of growth hormone deficiency, including Althea Technologies, Inc., Ambrx, Inc., Bioton S.A., Critical Pharmaceuticals, Ltd., Dong-A Pharmaceutical, GeneScience Pharmaceuticals Co., Ltd., Hanmi Pharmaceuticals Co., Ltd., Novo Nordisk A/S, OPKO Health, Inc., Teva Pharmaceutical Industries Ltd. and Versartis, Inc. Other companies are developing prostacyclin-based therapies to treat PAH, including Actelion Pharmaceuticals Ltd., GlaxoSmithKline LLC and United Therapeutics, and many small and large biopharmaceutical companies are developing therapies for diabetes and ophthalmic indications. In addition to product-based competition, our TransCon technology faces technology-based competition as we believe other companies are developing or evaluating enhanced drug delivery and sustained release technologies. In particular, we believe Nektar, Inc., OPKO Health, Inc., ProLynx LLC and Serina Therapeutics, Inc. are developing technologies that use reversible linkers and that may be competitive with our TransCon technology.

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

Furthermore, to the extent we are developing TransCon product candidates that incorporate already approved drugs, we face competition from the pharmaceutical companies which are currently marketing such approved

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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; 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.

For additional information regarding the competitive landscape for our product candidates, see “Business—TransCon Product Candidates.”

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

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

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

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

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

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

Our product candidates transiently link a parent drug molecule to select TransCon carriers via our TransCon linkers. Once injected, we believe that our prodrugs predictably release the unmodified parent drug molecule over time, thus preserving the parent drug's original mode of action, and, we believe, the parent drug's original safety and efficacy profile. We believe that our TransCon carriers remain bound to our TransCon linkers and that they are cleared from the body predominantly by renal filtration and biliary transport with fecal excretion. We have limited clinical data on product candidates utilizing the TransCon technology to indicate whether they are safe or effective for long-term use in humans, including the safety of any degradation products that may result after the TransCon carrier and TransCon linker are cleaved from the parent drug molecule. Our TransCon prodrugs utilize polyethylene glycol, or PEG, and hydrogels incorporating PEG-based polymers. The safety and efficacy of PEG and PEGylated proteins is demonstrated with the approval of drugs such as PegIntron®, PegaSys®, Neulasta®, Somavert®, Cimzia® and Krystexxa®. Although we are not aware of any evidence for PEG-related safety issues with PEGylated proteins in the clinic, health authorities, including the EMA, have

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raised questions relating to the disposition of PEG, particularly for PEGylated proteins used chronically and/or in the pediatric population. If treatment with any of our product candidates in our ongoing or future clinical trials results in concerns about their safety or efficacy, we and our collaboration partners may be unable to successfully develop or commercialize any or all of our TransCon technology based product candidates or enter into collaborations with respect to our product candidates.

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

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

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

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

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

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

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

We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing our products and product candidates for the potential pivotal clinical studies and/or commercial manufacturing of our

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products and product candidates. We depend on our collaboration partners and other third parties to produce and provide analytical services with respect to our lead product candidates.

In addition, if our product candidates are approved, in order to produce the quantities necessary to meet anticipated market demand, we and/or our collaboration partners will need to secure sufficient manufacturing capacity with third-party manufacturers. If we and/or our collaboration partners are unable to produce our product candidates in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, our revenues and gross margins could be adversely affected. To be successful, our product candidates must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. We and/or our collaboration partners will regularly need to secure access to facilities to manufacture some of our product candidates commercially. All of this will require additional funds and inspection and approval by the Competent Authorities of the Member States of the EEA, the FDA and other regulatory agencies. 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 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.

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 agency cGMPs requirements. We do not control the manufacturing process of our product candidates, and, other than with respect to our collaboration product candidates, we are dependent on our contract manufacturing partners for compliance with cGMPs regulations for manufacture of both active drug substances and finished drug products. If we or our collaboration partners or any third-party manufacturer fails to maintain regulatory compliance, our business, financial condition and results of operations may be harmed, and the FDA, the Competent Authorities of the Member States of the EEA, or other regulatory authorities can impose regulatory sanctions that range from a warning letter to withdrawal of approval to seeking product seizures, injunctions and, where appropriate, criminal prosecution.

Under our agreements with our collaboration partners, the manufacturing of our collaboration product candidates are the responsibility of the applicable collaboration partner. We are entirely dependent on our collaboration partners for all aspects of the manufacturing and validation process, as well as providing all commercial supply

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of our collaboration product candidates. For additional information regarding the risks of our dependence on our collaboration partners, see the risk factors above “—We are substantially dependent on the success of our lead product candidates, which may not be successful in preclinical studies or clinical trials, receive regulatory approval or be successfully commercialized” and “—We depend on collaboration partners to develop and conduct clinical studies with, obtain regulatory approvals for, and manufacture, market and sell our collaboration product candidates, and if such collaboration partners fail to perform as expected, or are unable to obtain the required regulatory approvals for such product candidates, the potential for us to generate future revenue from such product candidates would be significantly reduced and our business would be significantly harmed.”

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

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

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

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

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

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

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require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

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

It is generally necessary for us to secure certain levels of insurance as a condition for the conduct of clinical studies. We believe that our product liability insurance for clinical studies is sufficient to cover claims. We currently maintain liability insurance with certain specified coverage limits. We cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop. We currently carry product liability insurance covering use in our clinical trials in the amount of \$8 million in the aggregate. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and 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 June 30, 2014, we had 53 full-time employees. As we and/or our collaboration partners advance our product candidates through the development and commercialization process, we will need to expand managerial, operational, financial and other resources in order to manage our operations, preclinical and clinical trials, research and development activities, regulatory filings, manufacturing and supply activities, and any marketing and commercialization activities or contract with other organizations to provide these capabilities for us. As operations expand, we expect that we will need to manage additional relationships with various collaboration partners, suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures. Such growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we either internally, together with our collaboration partners or through third party contractors, as applicable:

- expand our general and administrative functions;

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

We will incur significant legal, accounting and other expenses as a publicly traded 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 will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will 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.

After this offering, we will be 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 second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least \$1 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our ordinary shares held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than an aggregate of \$1 billion in non-convertible debt during the prior three-year period.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, 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

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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 or our independent registered public accounting firm 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 our ordinary shares to fall. In addition, as a public company we will be 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 our ordinary shares from The NASDAQ Global 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 lead product candidates;
- the initiation of intellectual property litigation by third parties;
- the amount and timing of operating costs and capital expenditures relating to the expansion of our business operations and facilities;
- the timing of the commencement, completion or termination of collaboration agreements;
- the timing and amount of payments to us under our collaboration agreements, if any;
- the introduction of new products and services by us, our collaboration partners or our competitors;
- delays in preclinical testing and clinical studies;
- changes in regulatory requirements for clinical studies;
- costs and expenses associated with preclinical testing and clinical studies; and
- payment of license fees for the right to use third-party proprietary rights.

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

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

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

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

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- 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;
- 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 the euro or the U.S. dollar. Further, potential future revenue may be derived from abroad, including from the United States. As a result, our business and share price 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 may be adversely affected.

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

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

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

- different regulatory requirements for drug approvals in foreign countries;
- differing U.S. and non-U.S. drug import and export rules;

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

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

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

Our growth hormone parent drug is supplied by Hospira Adelaide Pty Ltd., and our drug substance and drug product for TransCon hGH are made by Rentschler Biotechnologie GmbH, or Rentschler, pursuant to our agreement with Rentschler. The intermediates of our proprietary TransCon linkers are made by CARBOGEN AMCIS AG under an agreement with CARBOGEN AMCIS AG and accompanying purchase orders. For products that utilize soluble TransCon carriers, NOF EUROPE (Belgium) NV supplies PEG and is responsible for coupling it to our TransCon linkers. OctoPlus Development N.V. manufactures and supplies the hydrogel micro-particles that we utilize in products based on our TransCon hydrogel technologies. We do not currently have any other suppliers for the drug substance, drug product or other components of our product candidates and, although we believe that there are alternate sources of supply that could satisfy our clinical and commercial requirements, we cannot provide assurance that identifying alternate sources and establishing relationships with such sources would not result in significant delay in the development of our product candidates. Additionally, we may not be able to enter into supply arrangements with alternative suppliers on commercially reasonable terms or at all. A delay in the development of our product candidates or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers could have a material adverse impact upon our business.

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

An important element of our strategy is to develop new products and product candidates based on our TransCon technology. Research programs to identify new product candidates require substantial technical, financial and

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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.

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

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

In particular, we are highly dependent upon Jan Møller Mikkelsen, our President and Chief Executive Officer, and Harald Rau, Ph.D., our Chief Scientific Officer. The loss of services of either of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates.

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

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

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

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

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

Risks Related to Government Regulatory and Legal Requirements

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

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA, E.U. legislative bodies and other regulatory authorities in the United States, the EEA and other jurisdictions, which regulations differ from country to country. Neither we nor any of our collaboration partners is permitted to market any drug product in the United States until we receive marketing approval from the FDA. Equally, neither we nor any of our collaboration partners is permitted to market any drug product in the EEA until we receive a marketing authorization from the EMA or EEA Member State Competent Authorities. We have not submitted an application or obtained marketing approval for any of our product candidates anywhere in the world. Obtaining regulatory approval of a new drug application, or NDA, or marketing authorization, can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S., EEA and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

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

Prior to obtaining approval to commercialize a drug candidate in the United States, the EEA or abroad, we or our collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the EMA, the FDA or other similar regulatory agencies, that such drug candidates are safe and effective for their intended uses. The number of nonclinical studies and clinical trials that will be required for FDA, or EMA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data

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for our drug candidates are promising, such data may not be sufficient to support approval by the EMA, the FDA and other regulatory authorities. Administering drug candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the EMA, the FDA or other regulatory authorities denying approval of a drug candidate for any or all targeted indications.

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

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

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

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

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

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

If we are unable to file an MAA for approval to the EMA for our product candidates, or if we are required to generate additional data related to safety and efficacy, in order to obtain approval under Sections 505(b)(1) or 505(b)(2) of the FDA for any of our product candidates, we may be unable to meet our anticipated development and commercialization timelines.

In certain circumstances, such as with TransCon hGH, we plan to submit NDAs for our product candidates under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the Act. Section 505(b)(2) NDAs entail efforts to minimize data required in order to obtain marketing approval for a product candidate and therefore potentially a shortened development period for these applications. We cannot guarantee that any of our product candidates, including TransCon hGH, may be submitted under Section 505(b)(2) of the Act.

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

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 agencies. 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.

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

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

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

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

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

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

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

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

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

In the United States, advertising and promotional materials must comply with FDA rules in addition to other potentially applicable U.S. laws. In particular, the promotional claims that we would be permitted to make for our products would be limited to those supported by the approved product labeling. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the FDA's cGMP requirements. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. Sales, marketing, and scientific/educational grant programs must comply with the U.S. Anti-Kickback Statute, the False Claims Act, as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to U.S. consumer protection and unfair competition laws.

We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for our products. Promotional communications

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with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have FDA approval.

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

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

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

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

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

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

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

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

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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 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 and biologics 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 and biologics. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

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

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

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

We depend on third parties to manufacture products employing our technology. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. All entities involved in the preparation of product

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

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

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

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA, a supplemental NDA, a marketing authorization variation application or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies 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

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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.

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

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

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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 agencies and if we fail to do so we could be subject to sanctions that would harm our business.

Some participants in clinical trials of TransCon hGH have reported adverse medical events, including headache and fatigue. FDA, EEA, and foreign regulatory agency 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 agency could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

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

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

Failure to obtain regulatory approvals in non-U.S. jurisdictions would prevent us from marketing our products internationally.

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

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

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

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

In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over

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existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the European Union and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension. For orphan-designated medicinal products, the 10-year period of market exclusivity is extended to 12 years. At this time, we have not agreed to a PIP with the PDCO for TransCon hGH, or any of our other product candidates.

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

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

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

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

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federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;

- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

Our success depends in part on our ability to:

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

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

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As of June 30, 2014, five patents have issued to us in the United States. Three of these patents are directed to our TransCon technology and one is directed to our current product candidates. In addition, as of June 30, 2014, we have approximately 27 issued patents in jurisdictions outside of the United States, at least 22 of which are directed to our TransCon technology, and five of which are directed to our product candidates. We are not aware of any challenge to our issued patents, in the United States, Europe or in any other jurisdiction.

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

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

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

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

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

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

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

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

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

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

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

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

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

Intellectual property litigation involves many risks and uncertainties, and there is no assurance that we will prevail in any lawsuit brought against us. Third parties making claims against us for infringement, violation or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Defense of these claims, regardless of their merit, would cause us to incur substantial expenses and, would be a substantial diversion of resources from our business. In the event of a successful claim of any such infringement, violation or misappropriation, we may need to obtain licenses from such third parties and we and our collaboration partners may be prevented from pursuing product development or commercialization and/or may be required to pay

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damages. We cannot be certain that any licenses required under such patents or proprietary rights would be made available to us, or that any offer to license would be made available to us on commercially reasonable terms. If we cannot obtain such licenses, we and our collaboration partners may be restricted or prevented from manufacturing and selling products employing our technology. These adverse results, if they occur, could adversely affect our business, results of operations and prospects, and the value of our shares.

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

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

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

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

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

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

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

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States do not afford intellectual property protection to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly 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 all countries outside the United States. 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

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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 this Offering

Our share price may be volatile and you may not be able to resell our ordinary shares at or above the price you paid.

The trading price of our ordinary shares following this offering 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 prospectus and others such as:

- results from, or any delays in, clinical trial programs relating to our product candidates, including the ongoing and future clinical trials for TransCon hGH and TransCon Treprostinil;
- ability to commercialize or obtain regulatory approval for our product candidates, or delays in commercializing or obtaining regulatory approval;
- announcements of regulatory approval or a complete response letter to our product candidates, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements relating to future collaborations or our existing collaborations, including decisions regarding the exercise by our collaboration partners of their options, if any, or any termination by them of their collaborations with us;
- timing and amount of payments to us under our collaborations, if any;
- announcements of therapeutic innovations or new products by us or our competitors;
- announcements regarding the parent drugs that we use in developing our product candidates;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our product candidates;
- any adverse changes to our relationship with any manufacturers or suppliers;
- the success of our testing and clinical trials;
- the success of our efforts to acquire or license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- EMA, FDA or other similar regulatory actions affecting us or our industry or other healthcare reform measures in the United States;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our ordinary shares;
- sales of our ordinary shares by us, our senior management and board members or our shareholders in the future;

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- 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 ordinary shares. 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 our shareholders 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.

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

Our senior management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways our shareholders may not agree with or that do not yield a favorable return, if at all. We intend to use substantially all of the net proceeds of this offering to fund the continued development of our proprietary TransCon product candidates, including the completion of our Phase 2 pediatric study of TransCon hGH, preparing to conduct a Phase 3 study of TransCon hGH, to further develop our TransCon Trepstinil and TransCon Osteoarthritis programs, to develop product candidates in new therapeutic areas, to strength our TransCon technology and for working capital and general corporate purposes. However, our use of these proceeds may differ substantially from our current plans. If we do not invest or apply the proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our share price to decline.

An active, liquid and orderly market for our ordinary shares may not develop, and you may not be able to resell your ordinary shares at or above the public offering price.

Prior to this offering, there has been no public market for our ordinary shares, and an active public market for our ordinary shares may not develop or be sustained after this offering. We and the underwriters will determine the initial public offering price of our ordinary shares through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our ordinary shares following this offering. In addition, an active trading market may not develop following the closing of this offering or, if it is developed, may not be sustained. The lack of an active market may impair your ability to sell your ordinary shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies or in-license new product candidates using our ordinary shares as consideration.

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, our share price and trading volume could decline.

The trading market for our ordinary shares will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our ordinary shares would be negatively impacted. In the event we obtain securities or industry analyst coverage, 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, our share price 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 our share price or trading volume to decline.

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Investors in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our ordinary shares is substantially higher than the pro forma net tangible book value per ordinary share before giving effect to this offering. Accordingly, if you invest in our ordinary shares in this offering, you will incur immediate substantial dilution of approximately \$ per share (€), based on the expected initial public offering price of \$ per share (€) (the midpoint of the price range set forth on the cover page of this prospectus), and our pro forma net tangible book value as of December 31, 2013. In addition, following this offering, investors in this offering will have contributed approximately % of the total gross consideration paid by shareholders to us to subscribe for our ordinary shares, but will own only approximately % of the ordinary shares outstanding immediately after this offering. Furthermore, if the underwriters exercise their option to subscribe for additional ordinary shares of our company, if board authorizations to issue additional shares or outstanding warrants or convertible securities are issued and subsequently exercised, you could experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see “Dilution.”

If we issue shares in future financings, shareholders may experience immediate dilution and, as a result, our share price may decline.

We may from time to time issue additional shares at a discount from the trading price of our ordinary shares. As a result, our shareholders would experience immediate dilution upon the issuance of any of our shares 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 shares or ordinary shares. If we issue shares or securities convertible into shares of our share capital, our ordinary shareholders would experience additional dilution and, as a result, our share price may decline.

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

If our existing shareholders sell, or indicate an intention to sell, substantial amounts of our ordinary shares in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our ordinary shares could decline. Based upon the number of shares outstanding as of June 30, 2014, upon the closing of this offering, we will have outstanding a total of ordinary shares, assuming no exercise of the underwriters’ option to subscribe for additional ordinary shares. Of these shares, approximately ordinary shares, plus any shares issued upon exercise of the underwriters’ option to subscribe for additional ordinary shares, will be freely tradable, without restriction, in the public market immediately following this offering. The underwriters, however, may, in their sole discretion, permit our senior management, board members and other shareholders who are subject to these lock-up agreements to sell ordinary shares prior to the expiration of the lock-up agreements.

The lock-up agreements pertaining to this offering will expire days from the date of this prospectus. After the lock-up agreements expire, up to an additional ordinary shares, as of June 30, 2014, will be eligible for sale in the public market, of which ordinary shares are held by current board members, senior management and other affiliates and may be subject to Rule 144 under the Securities Act.

There are, as of June 30, 2014, 613,225 warrants outstanding. If these warrants are exercised an additional 613,225 ordinary shares will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares could decline. Any sales of securities by these securityholders could have a negative effect on the trading price of our ordinary shares.

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

As of June 30, 2014, after giving effect to the closing of this offering, our senior management, board members, holders of 5% or more of our share capital and their respective affiliates will beneficially own approximately % of our outstanding voting securities (assuming no exercise of the underwriters' option to subscribe for additional ordinary shares and no exercise of outstanding warrants). As a result, these security holders will 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 that you may feel are in your best interest as one of our shareholders. 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 shares 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 our ordinary shares.

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, your interests as a shareholder. For a description of our governing documents and certain rights of our shareholders, see "Description of Share Capital."

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. The majority of our board members and employees reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the U.S. securities laws of the United States.

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

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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.

Upon closing of this offering, we will 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 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

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

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

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

We qualify as a foreign private issuer. As a result, in accordance with the listing requirements of The NASDAQ Global Market, we will rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of The NASDAQ Global 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

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a majority of our board consist of independent directors or the implementation of a 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 compensation 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, board member nomination procedures and approval of compensation of officers.

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 will vary 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 stock 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. For an overview of our corporate governance principles, see "Description of Share Capital." Accordingly, you 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, 2015 (the end of our second fiscal quarter in the fiscal year after this offering), 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, 2016. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must not be administered principally inside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and NASDAQ rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

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

While the determination of passive foreign investment company, or PFIC, status is fact specific, and generally cannot be made until the close of the taxable year in question, based on the value and composition of our assets,

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We may be a PFIC for U.S. federal income tax purposes for our current taxable year and future taxable years. A non-U.S. corporation will be considered a PFIC for any taxable year if either (1) at least 75% of its gross income for such year is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during such year) is attributable to assets that produce or are held for the production of passive income. Because the value of our assets for purposes of this determination will generally be determined by reference to the market price of our ordinary shares, our PFIC status will depend in large part on the market price of our ordinary shares. A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). If we are a PFIC for any taxable year during which a U.S. Holder (as defined in “Taxation—Material U.S. Federal Income Tax Consequences to U.S. Holders”) holds ordinary shares, 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 “Taxation—Material U.S. Federal Income Tax Consequences to U.S. Holders.”

We do not currently intend to pay dividends on our ordinary shares, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of 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, you are not likely to receive any dividends on your ordinary shares for the foreseeable future. Because we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our ordinary shares. There is no guarantee that our ordinary shares will appreciate or even maintain the price at which our holders have acquired them.

We are a Danish public limited liability company but will not be a listed company in Denmark, and shareholders of our company may have different and in some cases more limited shareholder rights than shareholders of a listed company in Denmark or of a U.S. listed company.

We are organized as a public limited liability company under the laws of Denmark. Our corporate affairs are governed by Danish corporate law, including the Danish Companies Act. From a Danish corporate law point of view, we qualify as a public company, but not as a listed company as none of our securities are listed on any regulated market in the European Economic Area, or the EEA. We have obtained confirmation from the Danish Business Authority and the Danish FSA that the Danish corporate law provisions that are applicable to Danish listed companies generally do not apply to us by virtue of this listing of our ordinary shares on The NASDAQ Global Market, unless the provision in question specifies that this is the case. We are thus not subject to most of the disclosure obligations applicable to Danish listed companies. As a result, shareholders of our company will not enjoy certain of the rights and protection generally afforded to shareholders of a Danish listed company. In the event that the Danish courts should take a different view on the interpretation of Danish legislation and the applicability due to a listing of the shares in the United States then there is a risk that holders of our ordinary shares will become subject to Danish regulations pertaining to companies with shares listed in the European Economic Area, or the EEA, which may make trading in our ordinary shares uncertain.

Investors should be aware that the rights provided to our shareholders under Danish corporate law and our articles of association differ in certain respects from the rights that you would typically enjoy as 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

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typically available to shareholders of U.S. companies, in order to enforce a right of our company, in case we fail to enforce such right ourselves, other than in certain cases of board member/management liability under limited circumstances. In addition, a majority of our shareholders may release a board member or manager from any claim of liability we may have, including if such board member or manager has acted in bad faith or has breached his/her duty of loyalty and only if a minority of at least 10% of the shareholders represented at the relevant general meeting have opposed the decision, may a shareholder bring a derivative action on behalf of our company. In contrast, most U.S. federal and state laws prohibit a company or its shareholders from releasing a board member from liability altogether if such board member has acted in bad faith or has breached such board member's duty of loyalty to our company. Additionally, distribution of dividends from Danish companies to foreign companies and individuals can be eligible for non-refundable withholding tax, and not all receiving countries allow for deduction. Also, the rights as a creditor may not be as strong under Danish insolvency law, as under U.S. law or other insolvency law, and consequently creditors may recover less in the event our company is subject to insolvency compared to a similar case including a U.S. debtor. In addition, the use of the tax asset consisting of the accumulated tax deficit requires that we are able to generate positive taxable income and can be restricted by future amendments to Danish tax law. Finally, Danish corporate law may not provide appraisal rights in the case of a business combination equivalent to those generally afforded a shareholder of a U.S. company under applicable U.S. laws. For additional information on these and other aspects of Danish corporate law and our articles of association, see the section herein entitled "Description of Share Capital." 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, you could receive less protection as a shareholder of our company than you would as a shareholder of a U.S. company.

Holders of our ordinary shares may not be able to exercise their pre-emptive subscription rights and may suffer dilution of their shareholding 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 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 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 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 of such shareholders may be materially diluted in the event shares are issued in the future. Shares 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 held by the shareholder in question. Rights issues may also be carried out by the board of directors according to valid authorizations in our articles of association.

Beneficial holders of our ordinary shares through the Depository Trust Company will not have direct rights as shareholders and must act through their participating broker to exercise their shareholder rights.

Cede & Co., as nominee for the Depository Trust Company, or DTC, will hold the ordinary shares in this offering on behalf of, and as nominee for, investors who invest in ordinary shares. We and DTC have no contractual relationship. Investors who invest in the ordinary shares (although recorded as owners within the DTC system) are legally considered holders of beneficial interests in those shares only and will have no direct rights as a shareholder against us. Investors who invest in ordinary shares in this offering must look solely to their participating brokerage in the DTC system for payment of dividends, the exercise of voting rights attaching to the ordinary shares and for all other rights arising with respect to the ordinary shares.

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Under our articles of association, the minimum notice period required to convene a general meeting is three weeks. When a general meeting is convened, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw your ordinary shares from the DTC system to allow you to directly cast your vote with respect to any specific matter. In addition, a participating DTC brokerage firm may not be able to send voting instructions to you or carry out your voting instructions in a timely manner. We cannot assure you that you will receive voting materials in time to ensure that you can instruct your participating DTC brokerage, or its designee, to vote your ordinary shares. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ordinary shares are not voted as you requested. In addition, if you hold your ordinary shares indirectly through the DTC system, you will not be able to call a shareholder meeting.

Because the Public Company Accounting Oversight Board is not currently permitted to inspect our independent accounting firm, you may not benefit from such inspections.

Auditors of U.S. public companies are required by law to undergo periodic Public Company Accounting Oversight Board, or PCAOB, inspections that assess their compliance with U.S. law and professional standards in connection with performance of audits of financial statements filed with the SEC. Certain European Union countries, including Denmark, do not currently permit the PCAOB to conduct inspections of accounting firms established and operating in such European Union countries, even if they are part of major international firms. Accordingly, unlike for most U.S. public companies, the PCAOB is prevented from evaluating our auditor's performance of audits and its quality control procedures, and, unlike shareholders of most U.S. public companies, we and our shareholders are deprived of the possible benefits of such inspections.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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 of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the timing of data from our ongoing Phase 2 pediatric study of TransCon hGH and the commencement of the Phase 1 studies of TransCon Treprostinil and the data from such study;
- our receipt of future milestone payments from our collaboration partners, and the expected timing of such payments;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- our expectations regarding the potential advantages of our prodrug product candidates over existing therapies;
- our potential to enter into new collaborations;
- our expectations with regard to the ability to develop additional product candidates using our TransCon platform and file INDs for such product candidates;
- our expectations with regard to the ability to seek expedited regulatory approval pathways for our product candidates, including the ability to rely on the parent drug’s clinical and safety data with regard to our prodrug product candidates;
- our expectations with regard to our current and future collaboration partners to pursue the development of our prodrug product candidates;
- our development plans with respect to our product candidates;
- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;
- the timing or likelihood of regulatory filings and approvals for our product candidates;
- the commercialization of our product candidates;
- our commercialization, marketing and manufacturing capabilities;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our use of proceeds from this offering;

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- our financial performance; and
- developments and projections relating to our competitors and our industry.

These forward-looking statements are based on management's current expectations, estimates, forecasts, and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development 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 prospectus 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 "Risk Factors" and elsewhere in this prospectus. Potential investors 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 prospectus. 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. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See "Where You Can Find More Information."

MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates, including data regarding the total sales of product in those markets, the estimated patient population in those markets, their projected growth rates, the perceptions and preferences of patients and physicians regarding the disease indications that we are pursuing or may pursue, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. For example, certain information contained in this prospectus regarding industry and market data was obtained from MedTRACK, a database of private and public biotechnology companies. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. Although we believe these sources are reliable, we have not independently verified the information contained in such publications. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "Special Note Regarding Forward-Looking Statements."

USE OF PROCEEDS

We estimate that the net proceeds from the sale of _____ ordinary shares in this offering will be approximately \$ _____ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, based on an assumed initial public offering price of \$ _____ per ordinary share (€ _____), the midpoint of the price range set forth on the cover page of this prospectus. If the underwriters exercise their option to subscribe for additional ordinary shares in full, we estimate that the net proceeds to us from this offering will be approximately \$ _____ million (€ _____ million) after deducting the underwriting commissions and estimated offering expenses payable by us. Each \$1.00 (€ _____) increase (decrease) in the assumed initial public offering price of \$ _____ per share (€ _____), the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting commissions and estimated offering expenses payable by us, by approximately \$ _____ million (€ _____ million), assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of ordinary shares we are offering. An increase (decrease) of 1,000,000 in the number of ordinary shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting commissions and estimated offering expenses payable by us, by approximately \$ _____ million (€ _____ million), assuming the assumed initial public offering price stays the same. We do not expect that a change in the offering price or the number of ordinary shares by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time until we need to seek additional capital.

The principal purpose of this offering is to increase our financial flexibility, create a public market for our ordinary shares and facilitate our access to the public equity markets. We intend to use the net proceeds from this offering, together with our existing cash resources to:

- pursue the development of TransCon hGH through the completion of our on-going Phase 2 pediatric clinical study, prepare for a Phase 3 pediatric study, including initiation of manufacturing activities for Phase 3 clinical trial material, and continued development of our pen device for delivery of TransCon hGH;
- further develop our TransCon Trepstinil and TransCon Osteoarthritis programs;
- identify and develop product candidates in new therapeutic areas where the benefits of our TransCon technology can be employed to address unmet medical needs or to create new best-in-class therapies;
- fund continued investment in our TransCon technology, including our intellectual property, our lab, clinical and commercial scale manufacturing capabilities and our methods and know-how; and
- fund working capital and general corporate purposes.

However, due to the uncertainties inherent in the clinical development and regulatory approval process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. As such, our senior management will retain discretion over the use of the net proceeds from this offering. The amounts and timing of any future cash needs will depend upon numerous factors, including the timing of the results of our ongoing Phase 2 trial of TransCon hGH, the receipt, if any, of milestone payments or up-front payments from one or more of our current or future collaboration partners, the size, scope and timing of any nonclinical studies or clinical trials that we may decide to pursue, and the number and scope of any discovery programs and research and development activities that we may undertake.

Pending the use of the proceeds from this offering, we intend to invest the net proceeds in interest-bearing, investment-grade securities, certificates of deposit or government securities.

DIVIDEND POLICY

We have never declared or paid cash dividends on our share capital. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

CAPITALIZATION

The following table sets forth our capitalization and cash and cash equivalents as of December 31, 2013:

- on an actual basis;
- on a pro forma basis to give effect to:
 - the conversion of all of our outstanding ordinary A, preference B and preference C shares into an aggregate of 2,700,487 ordinary shares immediately prior to the closing of this offering; and
 - the filing, registration and effectiveness of our articles of association, which will occur immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to the issuance of _____ ordinary shares in this offering at an assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

Actual data as of December 31, 2013 in the table below is derived from our audited consolidated financial statements. The pro forma and pro forma as adjusted data included in the table below is unaudited. You should read this information together with our audited consolidated financial statements appearing elsewhere in this prospectus and the information set forth under the headings “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of December 31, 2013		
	Actual	Pro Forma (EUR'000)	Pro Forma As Adjusted ⁽¹⁾
Cash and cash equivalents	19,430		
Equity:			
Share capital			
Ordinary A shares	43		
Preference B shares	37		
Preference C shares	282		
Other reserves	2,719		
Retained earnings	3,220		
Total equity	6,301		
Total capitalization	6,301		

(1) Each \$1.00 (€ _____) increase or decrease in the assumed initial public offering price of \$ _____ per ordinary share (€ _____), the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, respectively, the amount of cash and cash equivalents, total equity and total capitalization by \$ _____ million (€ _____ million), assuming the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting commissions, and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares we are offering. An increase or decrease of 1,000,000 in the number of ordinary shares we are offering would increase or decrease, respectively, the amount of cash and cash equivalents, total equity and total capitalization by approximately \$ _____ million (€ _____ million), assuming the assumed initial public offering price per share, as set forth on the cover page of this prospectus, remains the same. The pro forma information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

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The outstanding share information in the table above excludes the following:

- 312,452 ordinary shares issuable upon exercise of outstanding warrants with an expiration date of August 21, 2015 at a weighted average exercise price of (€12.7154) per share \$17.5385, as of December 31, 2013;
- 218,623 ordinary shares issuable upon exercise of outstanding warrants with an expiration date of August 21, 2023 at a weighted average exercise price of (€31.9847) per share \$44.1168, as of December 31, 2013; and
- 82,671 ordinary shares issuable upon exercise of warrants pursuant to future warrant grants as of December 31, 2013.

DILUTION

If you invest in our ordinary shares in this offering, your interest will be immediately diluted to the extent of the difference between the initial public offering price per ordinary share in this offering and the net tangible book value per ordinary share after this offering. As of June 30, 2014, we had a historical net tangible book value of \$() million (€ million), or \$ per ordinary share (€). Our net tangible book value represents total consolidated tangible assets less total consolidated liabilities and, all divided by the number of ordinary shares outstanding on June 30, 2014. Our pro forma net tangible book value at June 30, 2014, before giving effect to this offering, was \$ million (€ million), or \$ per ordinary share (€). Pro forma net tangible book value, before the issuance and sale of ordinary shares in this offering, gives effect to:

- the conversion of all of our outstanding ordinary A, preference B and preference C shares into an aggregate of 2,700,487 ordinary shares immediately prior to the closing of this offering; and
- the filing, registration and effectiveness of our articles of association, which will occur in connection with the closing of this offering.

After giving effect to the sale of ordinary shares in this offering at an assumed initial public offering price of \$ per share (€), the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting commissions and estimated offering expenses, our pro forma as adjusted net tangible book value at June 30, 2014 would have been approximately \$ million (€ million), or \$ per share (€). This represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share (€) to existing shareholders and an immediate dilution of \$ per share (€) to new investors. The following table illustrates this per share dilution:

Assumed initial public offering price per share	\$
Historical net tangible book value per share as of June 30, 2014	
Pro forma increase in net tangible book value per share	
Pro forma net tangible book value per share as of June 30, 2014	
Increase in pro forma net tangible book value per share attributable to new investors	
Pro forma as adjusted net tangible book value per share after this offering	
Dilution per share to new investors participating in this offering	

A \$1.00 increase (€) (decrease) in the assumed initial public offering price of \$ per ordinary share (€), the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value as of June 30, 2014 after this offering by approximately \$ million (€ million), or approximately \$ per share (€), and would decrease (increase) dilution to investors in this offering by approximately \$ per share (€), assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the underwriting commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of ordinary shares we are offering would increase (decrease) our pro forma as adjusted net tangible book value as of June 30, 2014 after this offering by approximately \$ million (€ million), or approximately \$ per share (€), and would decrease (increase) dilution to investors in this offering by approximately \$ per share (€), assuming the assumed initial public offering price per share remains the same, after deducting the underwriting commissions and estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

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If the underwriters fully exercise their option to subscribe for additional ordinary shares, pro forma as adjusted net tangible book value after this offering would increase to approximately \$ _____ per ordinary share (€ _____), and there would be an immediate dilution of approximately \$ _____ per share (€ _____) to new investors.

To the extent that outstanding warrants with an exercise price per ordinary share that is less than the pro forma as adjusted net tangible book value per share, before giving effect to the issuance and sale of ordinary shares in this offering, are exercised, new investors will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

The following table shows, as of June 30, 2014, on a pro forma as adjusted basis, after giving effect to the pro forma adjustments described above, the number of ordinary shares subscribed for from us, the total consideration paid to us and the average price paid per share by existing shareholders and by new investors purchasing ordinary shares in this offering at an assumed initial public offering price of \$ _____ per share (€ _____), the midpoint of the price range set forth on the cover page of this prospectus, before deducting the underwriting commissions and estimated offering expenses payable by us (in thousands, except share and per share amounts and percentages):

	<u>Shares Subscribed for</u>		<u>Total Consideration</u>		<u>Average Price Per Share</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	
Existing shareholders		%	\$	%	\$
Investors participating in this offering		%	\$	%	\$
Total		100%	\$	100%	\$

The number of ordinary shares to be outstanding after this offering is based on the number of shares outstanding as of June 30, 2014 and excludes the following:

- 312,452 ordinary shares issuable upon exercise of outstanding warrants with an expiration date of August 21, 2015 at a weighted average exercise price of €12.7154 per share (\$17.3471);
- 300,773 ordinary shares issuable upon exercise of outstanding warrants with an expiration date of August 21, 2023 at a weighted average exercise price of €31.9847 per share (\$43.6353); and
- 521 ordinary shares reserved for issuance pursuant to future warrant grants.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables present our selected consolidated financial data for our business. We derived the selected consolidated statement of profit or loss and other comprehensive income data and selected consolidated cash flow statement data for the years ended December 31, 2013 and 2012 and the selected consolidated statement of financial position data as of December 31, 2013 and 2012 and January 1, 2012 from our audited consolidated financial statements included elsewhere in this prospectus, which have been prepared in accordance with IFRS as issued by the IASB. You should read this data together with our audited consolidated financial statements and related notes appearing elsewhere in this prospectus and the information under the captions “Capitalization” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results are not necessarily indicative of our future results.

Selected Consolidated Statement of Profit or Loss and Other Comprehensive Income Data:

	Year Ended December 31,	
	2013⁽¹⁾	2012
	(EUR'000, except share and per share data)	
Revenue	20,408	15,583
Research and development costs	(12,713)	(11,380)
General and administrative expenses	(2,416)	(2,690)
Operating profit	5,279	1,513
Finance income	158	4
Finance expenses	(732)	(232)
Profit before tax	4,705	1,285
Tax on profit for the year	(626)	(35)
Net profit for the year	4,079	1,250
Other comprehensive income		
<i>Items that may be reclassified subsequently to profit or loss:</i>		
Exchange differences on translating foreign operations	(6)	(51)
Other comprehensive loss for the year, net of tax	(6)	(51)
Total comprehensive income for the year, net of tax	4,073	1,199
Profit for the year attributable to owners of the Company	4,079	1,250
Total comprehensive income for the year attributable to owners of the Company	4,073	1,199
	EUR	EUR
Basic and diluted earnings per share, preference C shares ⁽²⁾	1.94	0.57
Basic and diluted earnings per share, preference B shares ⁽²⁾	—	—
Basic and diluted earnings per share, ordinary shares ⁽²⁾	—	—

- (1) The year ended December 31, 2013 has been restated for the correction of an error. See Note 1 to our consolidated financial statements for more information.
- (2) For additional information regarding our basic and diluted earnings per share, see our Consolidated Statements of Profit or Loss and Other Comprehensive Income included in our consolidated financial statements.

[Table of Contents](#)**Selected Consolidated Statement of Financial Position Data:**

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

	<u>As of December 31,</u>		<u>As of January 1,</u>
	<u>2013⁽¹⁾</u>	<u>2012</u>	<u>2012</u>
	(EUR'000)		
Cash and cash equivalents	19,430	14,535	15,683
Total assets	26,700	25,405	22,818
Total liabilities	20,399	23,849	22,585
Retained earnings/(accumulated deficit)	3,220	(860)	(2,109)
Total equity	6,301	1,556	233

(1) The year ended December 31, 2013 has been restated for the correction of an error. See Note 1 to our consolidated financial statements.

Selected Consolidated Cash Flow Statement Data:

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

	<u>Year Ended December 31,</u>	
	<u>2013</u>	<u>2012</u>
	(EUR'000)	
Cash flows from/(used in) operating activities	6,310	(652)
Cash flows used in investing activities	(1,195)	(291)
Cash flows used in financing activities	(220)	(205)

EXCHANGE RATE INFORMATION

Our business is primarily conducted in the European Union, and we maintain our books and records in euros. We have presented results of operations in euros. On August 1, 2014, the exchange rate was € 0.733 to \$1.00. In this prospectus, financial figures included or extracted from our audited consolidated financial statements have been translated in accordance with the guidelines under IFRS. For convenience of the reader, this prospectus 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 the rate of €0.733 to \$1.00, the official exchange rate quoted as of June 30, 2014 by the European Central Bank. Such U.S. dollar amounts are not necessarily indicative of the amounts of U.S. dollars that could actually have been purchased upon exchange of euros at the dates indicated. The rates set forth below are provided solely for your convenience and may differ from the actual rates used in the preparation of our consolidated financial statements and other financial data included in this prospectus.

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

	<u>Period-end</u>	<u>Average for period</u> (€ per U.S. dollar)	<u>Low</u>	<u>High</u>
Year Ended December 31:				
2009	0.694	0.717	0.661	0.796
2010	0.748	0.754	0.687	0.837
2011	0.773	0.718	0.672	0.776
2012	0.758	0.778	0.743	0.827
2013	0.725	0.753	0.724	0.783
Month Ended:				
February 28, 2014	0.731	0.733	0.727	0.741
March 31, 2014	0.727	0.723	0.719	0.729
April 30, 2014	0.722	0.724	0.720	0.730
May 31, 2014	0.734	0.728	0.719	0.735
June 30, 2014	0.733	0.735	0.733	0.739
July 31, 2014	0.746	0.738	0.731	0.746

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the information contained within "Selected Consolidated Financial Data" and our audited consolidated financial statements, including the notes thereto, included in this prospectus. The following discussion is based on our financial information prepared in accordance with IFRS as issued by the IASB included within this prospectus, which might differ in material respects from generally accepted accounting principles in other jurisdictions. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described under "Risk Factors" and elsewhere in this prospectus.

Overview

We are applying our TransCon technology to develop a pipeline of long-acting prodrug therapies with best-in-class profiles that address large markets with significant unmet medical needs. Our TransCon technology establishes a new paradigm that combines the benefits of conventional prodrug and sustained release technologies, and is broadly applicable to proteins, peptides and small molecules. TransCon prodrugs predictably release unmodified active parent drugs and may offer advantages that include superior efficacy, safety, tolerability and compliance, including less frequent dosing and the ability to switch patients to subcutaneous injections from burdensome continuous infusions and less frequent dosing. We can design TransCon prodrugs to act systemically or locally in areas that are difficult to treat with conventional therapies. We believe that our TransCon technology has been validated by the clinical development of our wholly-owned Phase 2 product candidate, TransCon hGH, for the treatment of growth hormone deficiency, the acceptance of an IND for our TransCon Treprostinil for the treatment of pulmonary arterial hypertension, as well as by our multi-product collaborations with Sanofi and Genentech. We hold worldwide rights to our TransCon technology and have no third-party payment obligations with respect to our TransCon technology or any of our product candidates. All of our TransCon prodrugs are new molecular entities and should therefore be eligible to be granted new intellectual property rights, including new composition of matter patents.

We commenced operations in December 2007 when we acquired Complex Biosystems GmbH, the company that invented the TransCon technology. Since we commenced operations in 2007, we have devoted substantially all of our efforts to developing our product candidates, including conducting preclinical studies and clinical trials and providing general and administrative support for these operations. We do not have any approved products and have never generated any revenue from product sales. Since our inception through June 30, 2014, we have funded our operations through the sale of €24.4 million of our preference shares and convertible debt securities, and we have received aggregate gross proceeds of approximately €65 million from collaboration partners for up-front technology licensing fees, assignment of certain intellectual property rights and for services rendered under those agreements.

We had a net profit of €4.1 million for the year ended December 31, 2013 and €1.3 million for the year ended December 31, 2012. As of December 31, 2013, our retained earnings were €3.2 million compared to an accumulated deficit of €0.9 million as of December 31, 2012. We did not generate any revenues from royalties or product sales. We do not expect to generate royalty or revenues from product sales prior to regulatory approval of any of our product candidates.

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 have expressed substantial doubt regarding our ability to continue as a going concern in our consolidated financial statements included in this prospectus and our independent registered public accounting firm has included an explanatory paragraph in its report on our consolidated financial statements as of, and for the year ended, December 31, 2013 with respect to this uncertainty. A report with this type of explanatory paragraph could impair our ability to finance our operations

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through collaboration agreements, or the sale of debt or equity securities or to obtain commercial bank loans. Our ability to continue as a going concern will depend, in large part, on our ability to obtain necessary financing, which is uncertain. Our failure to obtain sufficient funds on acceptable terms when needed could harm our business, results of operations, and financial condition. See “Liquidity and Capital Resources” and Note 1 in “Notes to Consolidated Financial Statements” for additional information describing the circumstances that led to the inclusion of this disclosure in the consolidated financial statements and the explanatory paragraph in the audit report.

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

- pursue the development of TransCon hGH through the completion of our ongoing Phase 2 pediatric clinical study, prepare for a pediatric Phase 3 study, including initiation of manufacturing activities for Phase 3 clinical trial material, and continued development of our proprietary pen device for delivery of TransCon hGH;
- further develop our TransCon Trepstinil and TransCon Osteoarthritis programs;
- identify and develop product candidates in new therapeutic areas where the benefits of our TransCon technology can be employed to address unmet medical needs or to create new best-in-class therapies;
- continue to investment in our TransCon technology, including our intellectual property, our lab, clinical and commercial scale manufacturing capabilities and our methods and know-how;
- hire additional personnel, particularly in our research and development, clinical supply and quality control groups;
- add operational, financial and management information systems and related finance and compliance personnel; and
- operate as a public company.

Collaboration Agreements

Sanofi

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

In consideration for these licenses to the TransCon technology and as payment for the assignment of specific diabetes-related product patents, Sanofi provided 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 fixed payments upon Sanofi’s achievement of specified clinical development and regulatory approval milestones and a specified payment upon Sanofi’s achievement of certain sales-related milestones.

Genentech

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

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retinopathy. We also granted to Genentech a worldwide, non-exclusive, royalty-bearing license to make, use and commercialize such products to treat diabetic retinopathy.

In consideration for these licenses, Genentech paid us a non-refundable up-front technology license fee of \$20.0 million (€15.0 million), and we are eligible to receive milestone payments upon Genentech's achievement of specified development milestones for all licensed products Genentech develops under the agreement, and upon the first commercial sale of these products in various markets. We are also eligible to receive tiered royalties on net sales of all products commercialized under the agreement at percentages ranging from the mid-single digits to the low double digits, subject to customary reductions and offsets. Genentech also provides funding for our research and development activities under an agreed-upon plan.

United Therapeutics

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

Financial Operations Overview

Revenue

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

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

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

Research and Development Costs

Research and development costs represent costs incurred to conduct discovery and development of our proprietary product candidates as well as research and development of product candidates for our collaboration

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

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

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

Government grants are recognized when there is reasonable assurance that the conditions underlying the grant have been met and that the grant will be received. In 2013 and 2012, we received grants from the German Bundesministerium for development activities related to early stage research applying our TransCon technology to various therapeutic compounds and disease categories. Government grants to cover research and development costs incurred are recognized as a reduction of research and development costs proportionally over the periods during which the related research and development expenses are incurred.

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

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

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

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

General and Administrative Expenses

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

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We expect our general and administrative expenses to increase substantially 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 following the closing of this offering, including increased expenses related to legal, accounting, regulatory and tax-related services associated with maintaining compliance with the rules and regulations applicable to companies listed on a securities exchange, and costs related to compliance and reporting obligations pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC. In addition, we expect to incur increased expenses related to additional insurance, investor relations activities and other increases related to needs for additional administration and professional services associated with being a public company.

Finance Income and Finance Expenses

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

Results of Operations

The following table provides a comparison of the years ended December 31, 2013 and 2012:

	Year ended December 31,	
	2013 ⁽¹⁾	2012
	(EUR'000)	(EUR'000)
Revenue	20,408	15,583
Research and development costs	(12,713)	(11,380)
General and administrative expenses	(2,416)	(2,690)
Operating profit	5,279	1,513
Finance income	158	4
Finance expenses	(732)	(232)
Profit before tax	4,705	1,285
Tax on profit for the year	(626)	(35)
Net profit for the year	4,079	1,250

(1) The year ended December 31, 2013 has been restated for the correction of an error. See Note 1 to our consolidated financial statements for more information.

Revenue

The following table summarizes our revenue for the years ended December 31, 2013 and 2012:

	Year ended December 31,	
	2013	2012
	(EUR'000)	(EUR'000)
Revenue from the rendering of services	4,161	5,191
License income	16,247	10,392
Total revenue	20,408	15,583

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Total revenue for the year ended December 31, 2013 was €20.4 million, an increase of €4.8 million, or 31%, compared to total revenue of €15.6 million for the year ended December 31, 2012. This increase in revenue is primarily due to the full and partial year effects on revenue related to payments under our collaborations with United Therapeutics and Genentech, respectively, for the years ended December 31, 2013 as compared to the year ended December 31, 2012. In the year ended December 31, 2013, we had a €3.8 million increase in revenue from United Therapeutics primarily due to the full-year effect of the revenue in the year ended December 31, 2013 as compared to only six months of revenue under the agreement for the year ended December 31, 2012. In the year ended December 31, 2013, we had a €3.5 million increase in revenue that resulted from an up-front payment we received upon entering into a collaboration agreement with Genentech in July 2013 as compared to no revenue from our collaboration with Genentech in the year ended December 31, 2012. Revenue from our collaboration agreement with Sanofi decreased by €1.0 million and revenue from feasibility studies decreased by €1.5 million for the year ended December 31, 2013 as compared to the year ended December 31, 2012.

As of December 31, 2013, we had deferred income of €17.5 million arising from collaboration agreements compared to €21.1 million as per December 31, 2012. This deferred income will be recognized as revenue as our collaboration partners progress their development projects.

Research and Development Costs

Research and development costs increased to €12.7 million for the year ended December 31, 2013 from €11.4 million for the year ended December 31, 2012. The increase of €1.3 million, or 11%, is primarily attributable to a €1.3 million increase in personnel costs related to an increase in the number of employees in research and development functions. External costs associated with our proprietary product candidate TransCon hGH decreased by approximately €1.0 million following the high costs for the year ended December 31, 2012, building up to initiation of the Phase 2 pediatric study. This decrease was offset by increasing costs incurred for the year ended December 31, 2013 as we furthered development of our TransCon Osteoarthritis program and other early stage programs.

We also received €0.4 million in grants from the German Bundesministerium in 2013 compared to €0.3 million in 2012. Such grants have been offset against the research and development costs for the respective years.

General and Administrative Expenses

General and administrative expenses were €2.4 million for the year ended December 31, 2013, a decrease of €0.3 million, or 11%, compared to general and administrative expenses of €2.7 million for the year ended December 31, 2012. Our overhead expenses are allocated to general and administrative and research and development functions based on the proportion of general and administrative to research and development employees. In 2013, we increased the number of our research and development employees relative to our general and administrative employees. The €0.3 million reduction in general and administrative expense was primarily due to this proportional change of employees in our general and administrative and research and development departments.

Finance Income and Finance Expenses

Finance income increased by €154,373 to €158,269 for the year ended December 31, 2013 compared to €3,896 for the year ended December 31, 2012. Finance expenses also increased by €499,429 to €731,704 for the year ended December 31, 2013 compared to €232,275 for the year ended December 31, 2012. On a net basis, net finance expenses were €0.6 million for the year ended December 31, 2013, a net increase of €0.4 million compared to €0.2 million for the year ended December 31, 2012. The increase in net expenses was due to exchange rate fluctuations, primarily with respect to the cash position maintained in USD, as the exchange rate between USD and EUR weakened over the year ended December 31, 2013.

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Tax on Profit for the Year

Tax on profit for the year was €0.6 million for the year ended December 31, 2013 compared to €35,063 for the year ended December 31, 2012. €0.2 million of the tax provision for the year ended December 31, 2013 relates to our German subsidiary, which had a taxable income exceeding its tax losses carried forward, whereas in 2012 the taxable income was offset by tax losses carried forward. Ascendis Pharma A/S and our Danish subsidiaries are subject to joint taxation with the benefit of offsetting tax profits and tax losses, however with certain restrictions on the offsetting within each fiscal year. For the year ended December 31, 2013, these jointly taxed entities had a taxable income which could not be fully offset by tax losses carried forward due to such restrictions, and accordingly, a tax provision of €0.4 million was recognized. For the year ended December 31, 2012, tax profits within these jointly taxed entities was fully offset by tax losses, and no tax provisions were recognized. The tax provision for the year ended December 31, 2012 was solely related to our subsidiary in the United States.

At December 31, 2013 and 2012, we had net deferred tax assets of €6.8 million and €7.7 million, respectively, which were not recognized in the consolidated statement of financial position due to uncertainties relating to the future utilization. The decrease in the unrecognized deferred tax asset can primarily be attributed to a decrease in tax losses carried forward. The deferred tax asset can be carried forward without timing limitations. Limitations on amounts to be used each year exist.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2013:

<u>Contractual Obligations:</u>	<u>Payments Due by Period</u>				<u>Total</u>
	<u>Less Than 1 Year</u>	<u>1 to 3 Years</u>	<u>3 to 5 Years</u>	<u>More Than 5 Years</u>	
	(EUR'000)				
Operating Lease Obligations ⁽¹⁾⁽²⁾	€577	€138	-	-	€715
Total contractual obligations	<u>€577</u>	<u>€138</u>	<u>-</u>	<u>-</u>	<u>€715</u>

- (1) Operating Lease Obligations primarily comprise leased offices in Denmark and the United States, and leased offices and laboratories in Germany.
- (2) Subsequent to December 31, 2013, the lease term of our offices and laboratories in Germany was extended by 24 months to expire on January 31, 2017. The additional commitment amount is €0.7 million, the majority of which is payable between 1 to 3 years from December 31, 2013.

Liquidity and Capital Resources

As of December 31, 2013 and 2012, we had cash and cash equivalents totaling €19.4 million, and €14.5 million, respectively. We have funded our operations primarily through issuance of our preference 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.

We believe that our existing cash and cash equivalents as of December 31, 2013, along with the proceeds from this offering, will be sufficient to meet our projected cash requirements for at least 12 months from the date of this prospectus. 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. As a result of our cash position and our need for additional sources of capital to fund our ongoing operations, we have expressed substantial doubt regarding our ability to continue as a going concern in our consolidated financial statements in this prospectus as of, and for the year ended, December 31, 2013 and our independent registered public accounting firm has included an explanatory paragraph in its report to our consolidated financial statements with respect to this uncertainty. 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;

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- 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 that have not been licensed, including the ability to enroll patients in a timely manner for clinical trials;
- the time and cost necessary to obtain regulatory approvals for our product candidates that have not been licensed and the costs of post-marketing studies that could be required by regulatory authorities;
- our progress and the progress of our collaboration partners in the successful commercialization and co-promotion of our lead product candidates and our efforts to develop and commercialize our other existing product candidates;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the number and scope of preclinical and discovery programs that we decide to pursue or initiate;
- the potential acquisition and in-licensing of other technologies, products or assets;
- the time and cost necessary to respond to technological and market developments, including further development of our TransCon technology; 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 June 30, 2014, we have funded our operations through the sale of €24.4 million of our preference shares and convertible debt securities, and we have received aggregate gross proceeds of approximately €65 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, 2013 and 2012:

	Year ended December 31,	
	2013	2012
	(EUR'000)	(EUR'000)
Cash flows from/(used in) operating activities	6,310	(652)
Cash flows used in investing activities	(1,195)	(291)
Cash flows used in financing activities	(220)	(205)
Net increase / (decrease) in cash and cash equivalents	4,895	(1,148)

Cash flows from/(used in) Operating Activities

Cash flows from operating activities for the year ended December 31, 2013 were €6.3 million compared to cash flows used in operating activities of €0.7 million for the year ended December 31, 2012. The net profit for the year ended December 31, 2013 was €4.1 million, which was partially offset by non-cash charges of €0.4 million for depreciation and €0.7 million for share-based payments. Further, net finance charges, primarily comprising

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exchange rate adjustments of €0.6 million, and tax charges of €0.6 million, were reversed. The net change in working capital of €0.5 million was primarily comprised of a reduction in receivables, related to up-front payments and payments for services rendered, from our collaboration partners of €4.0 million that was partially offset by €3.6 million from the recognition of deferred income.

Cash flows used in operating activities for the year ended December 31, 2012 was €0.7 million. The net profit for the year of €1.3 million was partially offset by non-cash charges of €0.4 million for depreciation and €0.1 million for share-based payments. Further, net finance charges, primarily comprising exchange rate adjustments of €0.2 million, and tax charges of €35,063, were reversed. The working capital was decreased by €2.5 million, primarily affected by an increase in receivables, related to up-front payments and payments for services rendered of €4.5 million that was partially offset by a decrease in deferred income of €1.4 million.

Cash Flows Used in Investing Activities

Cash flows used in investing activities for the year ended December 31, 2013 of €1.2 million solely related to the acquisition of property, plant and equipment, for use in the laboratories of our German facility. Similarly, cash used in investing activities for the year ended December 31, 2012 of €0.3 million also solely related to acquisition of property, plant and equipment for use in the laboratories of our German facility.

Cash Flows Used in Financing Activities

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

Cash flows used in financing activities for the year ended December 31, 2012 of €0.2 million solely related to installments on the lease arrangement for the laboratory equipment entered into in 2010 as described above.

Off-balance Sheet Arrangements

As of December 31, 2013 and 2012, we did not have any off-balance sheet arrangements or any holdings in variable interest entities.

Quantitative and Qualitative Disclosures about Market Risk

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

Foreign Currency Risk

We are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the U.S. dollar and the Danish Krone. Our functional currency is the euro, but we have received payments in U.S. dollars under our collaboration with Genentech and our prior collaboration with United Therapeutics. While we have not established a formal practice to manage foreign exchange risk against our functional currency, we maintain cash reserves denominated in the various currencies we need to run our operations and make payments from those reserves. At December 31, 2013, the carrying amount of our foreign currency denominated monetary assets and liabilities was €18.7 million, and we held \$21.2 million denominated in U.S. dollars.

Proceeds from this offering in U.S. dollars may be partially held in U.S. dollars and partially converted to our functional currency, the euro.

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

A sensitivity analysis of our exposure to USD based on outstanding foreign currency denominated monetary items as of December 31, 2012 shows that a strengthening of USD against EUR by 10% would increase net profit or loss and equity by €1.2 million. A 10% weakening of USD against EUR would decrease profit or loss and equity by a similar amount.

Interest Rate Risk

We are not directly exposed to interest rate risk because of our capital structure with no interest-bearing debt to third parties.

Credit Risk

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

Liquidity Risk

We manage our liquidity risk by maintaining adequate cash reserves at banking facilities, and by continuously monitoring our cash forecasts, our actual cash flows, and by matching the maturity profiles of financial assets and liabilities. We believe that our existing cash and cash equivalents as of December 31, 2013, along with the proceeds from this offering, will be sufficient to meet our projected cash requirements for at least the 12 months from the date of this prospectus. As a result of our cash position and our need for additional sources of capital to fund our ongoing operations, we have expressed substantial doubt regarding our ability to continue as a going concern in our consolidated financial statements included herein and our independent registered public accounting firm has included an explanatory paragraph in its report on our consolidated financial statements as of, and for the year ended, December 31, 2013 with respect to this uncertainty. See “Liquidity and Capital Resources” and Note 1 in “Notes to Consolidated Financial Statements” for additional information.

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, 2013 and 2012 included elsewhere in this prospectus. 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 revisions affects both current and future periods.

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Critical Accounting Policies

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

Revenue Recognition

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

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

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

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

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

Share-Based Payment

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

We recognize compensation costs related to these warrants based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. We estimate the grant date fair value, and the resulting share-based payment expense, using the Black-Scholes option-pricing model. The grant date fair value of the share-based awards is generally recognized on an accelerated basis over the requisite service period, i.e. each tranche of a warrant grant is treated separately for expense recognition purposes. Accordingly, each warrant grant is treated in up to 48 tranches, which are each recognized over the expected useful life of that particular tranche. Because our company's warrants vest on a monthly basis over periods up to 48 months, a higher percentage of total expense is recognized in the initial years after the grant date. Share-based payment expense was €0.7 million and €0.1 million for the years ended December 31, 2013 and 2012, respectively.

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

- *Expected Lifetime*—The expected lifetime of each individual warrant tranche represents the period that share-based awards are expected to be outstanding. The warrants may be exercised during two exercise periods of three weeks, each commencing on January 1 and August 1, respectively. The last exercise period for warrants granted during the period 2008 to 2012 expires in August 2015. For these warrants, the expected lifetime was based on the contractual term, as we expect these warrants to be exercised at the end of their contractual term. For the remaining warrants, which can be exercised until August 2023, we estimated the expected lifetime based on the weighted average of the time from grant date to date the warrants become exercisable and from grant date to expiry of the warrants, also considering the periods during which the warrants may be exercised.
- *Expected Volatility*—Since we are privately held and do not have any trading history for our ordinary shares, the expected volatility was estimated based on the average volatility for comparable publicly traded biopharmaceutical companies measured over a period equal to the expected lifetimes of the individual warrant tranches. When selecting comparable publicly traded biopharmaceutical companies on which we based our expected share price volatility, we selected companies with comparable characteristics to us, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to measure volatility over the expected lifetime of the share-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own share price becomes available.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the Danish government bond effective interest rate in effect at the time of grant with the same lifetime as the warrants.
- *Expected Dividend*—We have never paid dividends on our ordinary shares and have no plans to pay dividends on our ordinary shares. Therefore, we provided for no payment of dividends in the Black-Scholes option pricing model.

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

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

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In determining the fair value for our ordinary shares for periods up to December 31, 2012, we used the Option-Pricing Method, or OPM. For purposes of this method, we estimated the enterprise value based on the price of our most recent preference shares financing and consideration of incremental cash flows anticipated from milestone payments from our collaboration partners added after such financing. For periods subsequent to December 31, 2012, as there was less uncertainty regarding a potential exit event, we applied the hybrid method. Under the hybrid method, we estimated per-share values of our ordinary shares under different scenarios, using the Probability-Weighted Expected Return Method, or PWERM, for two of our exit scenarios, going public in twelve months and in eighteen months, and the OPM for the remaining scenario of continuing to operate as a private company. For purposes of PWERM, we applied the market approach to determine the enterprise value. The market approach estimates the fair value of a company through estimation of a future value to be realized in a future initial public offering based on recent comparable biopharmaceutical companies initial public offerings. Such value is discounted using an appropriate risk-adjusted discount factor based primarily on benchmark venture capital studies of discount rates for other companies in similar stages of development.

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

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

The intrinsic value of all outstanding warrants as of December 31, 2013 was € based on the assumed initial public offering price of our ordinary shares, which is the midpoint of the price range set forth on the cover page of this prospectus.

Internally Generated Intangible Assets

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

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

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

Joint Arrangements / Collaboration Agreements

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

Key Sources of Estimation Uncertainty

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

Impairment of Goodwill

As required under IFRS, we perform an impairment test of goodwill on an annual basis, or more frequently to the extent indicators of impairment exist. For the years ended December 31, 2013 and 2012, the recoverable amount of goodwill has been determined based on fair value less cost to sell. We determine the fair value of goodwill after taking into account the results of a third party valuation as of a corresponding consolidated statement of financial position date. The valuation methodologies we apply are based on a combination of a market approach, an option pricing method and a probability weighted expected return method.

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

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

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

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

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

Restatement of Previously Issued Consolidated Financial Statements

We filed our statutory annual report for the year ended December 31, 2013 with the Danish authorities on June 2, 2014, including our consolidated financial statements prepared under IFRS. Those consolidated financial statements did not appropriately reflect a tax charge for the fiscal year ended December 31, 2013. The tax calculation incorrectly assumed that certain tax losses carried forward could be fully offset against the taxable income earned in one of our subsidiaries. However, Danish tax law imposes limitations to the offsetting of tax losses against tax profits within each fiscal year, and accordingly, the taxable income could not be fully offset by the tax losses carried forward. As a result, an additional tax provision of €0.4 million has been recognized in our restated consolidated financial statements. See Note 1 to our consolidated financial statements for more information.

BUSINESS

Overview

We are applying our TransCon technology to develop a pipeline of long-acting prodrug therapies with best-in-class profiles that address large markets with significant unmet medical needs. Our TransCon technology establishes a new paradigm that combines the benefits of conventional prodrug and sustained release technologies, and is broadly applicable to proteins, peptides and small molecules. TransCon prodrugs predictably release unmodified active parent drugs and may offer advantages that include superior efficacy, safety, tolerability and compliance, including less frequent dosing and the ability to switch patients to subcutaneous injections from burdensome continuous infusions and less frequent dosing. We can design TransCon prodrug candidates to act systemically or locally in areas that are difficult to treat with conventional therapies. By primarily focusing on biological targets that have been clinically validated, we can leverage available knowledge regarding a target's activity. Based on this selective approach, we know what drug levels must be maintained in the body for optimal efficacy and safety, and we can design the release half-life of our TransCon prodrugs to maintain these levels to achieve the desired pharmacological effect. We move a product candidate into development after it demonstrates a superior profile in animal models that we believe correlate to human clinical experience. This strategy is designed to reduce risk and increase productivity.

We believe that our TransCon technology has been validated by the clinical development of our wholly-owned Phase 2 product candidate, TransCon hGH, for the treatment of growth hormone deficiency, the acceptance of an Investigational New Drug application, or an IND, for our TransCon Treprostinil for the treatment of pulmonary arterial hypertension, or PAH, as well as by our multi-product collaborations with Sanofi and Genentech. We hold worldwide rights to our TransCon technology and have no third-party payment obligations with respect to our TransCon technology or any of our product candidates. All of our TransCon prodrugs are new molecular entities and should therefore be eligible to be granted new intellectual property rights, including new composition of matter patents.

Our most advanced product candidate is TransCon human Growth Hormone, or TransCon hGH, for the treatment of growth hormone deficiency, or GHD. According to MedTRACK, global sales from currently marketed hGH products grew to over \$3 billion in 2013. The current standard of care for the treatment of GHD requires that patients, the majority of whom are children, receive daily injections over many years. The administrative burden of daily injections often results in poor patient compliance and can lead to suboptimal treatment outcomes. To address these unmet medical needs, we are developing TransCon hGH for once-weekly administration. Because TransCon hGH is a prodrug that releases unmodified growth hormone, TransCon hGH maintains the same mode of action as currently prescribed daily hGH therapies. Clinical studies of TransCon hGH have demonstrated a comparable efficacy, safety, tolerability and immunogenic profile to that of daily growth hormone. If approved, TransCon hGH may reduce the burden of daily treatment by requiring significantly fewer injections, which may improve compliance and treatment outcomes. We have successfully completed a Phase 2 study of TransCon hGH in adults with GHD and are currently enrolling children with GHD in a six-month Phase 2 study. In October 2014, we expect to report three-month data, including height velocity, from 50% of the patients in our Phase 2 pediatric study, and top-line data for all patients in the trial in the first half of 2015.

We are also developing TransCon Treprostinil for the treatment of PAH, a life-threatening disease characterized by elevated blood pressure in the pulmonary arteries. According to MedTRACK, the worldwide market for PAH treatment exceeded \$4 billion in 2013. Treprostinil, the active agent in United Therapeutics' product Remodulin®, belongs to a class of drugs known as prostacyclins, and is the leading infused therapy for the treatment of PAH. TransCon Treprostinil is designed as a once-daily self-administered subcutaneous injection, offering the same efficacy as continuously infused prostacyclins with a safer and improved tolerability profile. TransCon Treprostinil is expected to offer significant advantages as compared to current infused prostacyclin therapy, including minimizing infusion site pain and the risk of bloodstream infection. The U.S. Food and Drug Administration, or the FDA, has accepted an IND for TransCon Treprostinil.

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Our internal pipeline also includes TransCon product candidates intended for intra-articular administration in osteoarthritis, including TransCon Steroid. We are currently evaluating TransCon Steroid and other osteoarthritis candidates in preclinical models.

In addition to our proprietary programs, we have formed multi-product collaborations with leading biopharmaceutical companies on market-leading products and in therapeutic categories that are of strategic importance to our collaboration partners. These collaborations are as follows:

- Sanofi: TransCon Insulin in diabetes, and
- Genentech: TransCon Ranibizumab in age-related macular degeneration, or AMD, and other ophthalmic indications.

As of June 30, 2014, we have received approximately €65 million of non-dilutive financing from collaboration partners, and we are eligible to receive up to an additional aggregate of €220 million in development and regulatory milestone payments for products currently being developed under our collaboration agreements, as well as sales-based milestone payments and royalties on future net sales of products.

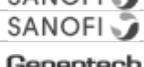
Our TransCon technology enables us to create long-acting prodrug therapies with significant advantages over existing marketed drug products. A prodrug is an inactive form of a parent drug that is designed to be activated only after it undergoes transformation in the body. Conventional prodrug technologies rely upon transformation by processes that cannot be controlled to facilitate predictable and sustained release of the parent drug.

Our TransCon technology is differentiated in that it enables us to design long-acting prodrugs that predictably release an unmodified active parent drug at predetermined rates governed only by physiological pH and temperature conditions. Because these conditions are tightly regulated in the body, we are able to design our TransCon prodrugs to predictably release an unmodified active parent drug over an extended period of time. In addition to retaining the original mode of action of the parent drug, TransCon prodrugs may offer advantages that include dosing frequencies from daily to half-yearly, a switch to subcutaneous injection from continuous infusion, and improved efficacy, safety and tolerability profiles.

When we apply our TransCon technology to already approved drug compounds, we may benefit from established clinical safety and efficacy data, which we believe reduces drug development risk and may allow us to utilize expedited approval pathways provided by the FDA and European regulatory agencies. All of our TransCon prodrugs are new molecular entities and should therefore be eligible to be granted new intellectual property rights, including new composition of matter patents.

TransCon Product Candidate Pipeline

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

Product Candidate	Primary Indication	Approved Parent Drug	Stage of Development	Market Size	Worldwide Commercial Rights
TransCon Human Growth Hormone	Pediatric Growth hormone deficiency	ü	Phase 2 (Interim data expected Oct 2014/ Top-Line data expected H1 2015)	> \$3 billion	
	Adult Growth hormone deficiency	ü	Phase 2 completed		
TransCon Treprostinil	Pulmonary Arterial Hypertension	ü	Accepted IND	> \$1 billion	
TransCon Steroid	Osteoarthritis (intra-articular administration)	ü	Preclinical	> \$1 billion	
TransCon Candidate(s)		ü	Preclinical		
TransCon Insulin	Diabetes	ü	Preclinical safety completed	>\$7 billion	
TransCon Peptide			Preclinical	n/a	
TransCon Ranibizumab	Ophthalmology	ü	Preclinical	> \$5 billion	

Examples of regulatory strategies that may be available to us or our collaboration partners include the FDA's section 505(b)(2) regulatory approval pathway, which was established to allow companies developing drug products to obtain approval by relying in part on studies of safety and effectiveness that were not conducted by or for the applicant. Because approval can rest in part on data already accepted by the FDA or otherwise available in the public domain, fewer and smaller studies may be required, thus mitigating costs and shortening development time. Section 505(b)(2) filings can provide expedited approval for a wide range of products, especially for those that represent a limited change from an existing or approved drug, including prodrugs of already approved parent drugs.

We maintain an intellectual property portfolio comprising approximately 30 issued patents and approximately 160 patent applications as of June 30, 2014, with claims directed to composition of matter, process, formulation and/or methods-of-use for our product candidates and core TransCon technology. In addition, each of our collaboration partners has granted us rights that enable us to freely commercialize all improvements to the TransCon technology developed by our collaboration partners outside of the field identified in their respective collaboration agreements. While our TransCon prodrugs may incorporate already approved parent drugs, each of our product candidates is a new molecular entity and is therefore eligible to be granted new intellectual property rights, including new composition of matter patents.

Our Strategy

Our goal is to leverage our TransCon technology to create a pipeline of proprietary products and form collaborations with market-leading biopharmaceutical companies to develop new products that incorporate our TransCon technology in therapeutic areas that are of strategic importance.

Key elements of our strategy to achieve this goal include:

- *Rapidly advance the development of our advanced product candidates, including our product candidates, TransCon hGH and TransCon Treprostinil:*
We have successfully completed a Phase 2

study of TransCon hGH in adults with GHD and are currently enrolling children with GHD in a six-month Phase 2 study. In October 2014, we expect to report three-month data, including height velocity, from 50% of the patients in our Phase 2 pediatric study, and top-line data for all patients in the trial in the first half of 2015. We are also developing TransCon Treprostinil for the treatment of PAH and in June 2014 the FDA accepted an IND for TransCon Treprostinil.

- *Leverage our TransCon technology to create a pipeline of new product candidates with best-in-class therapeutic profiles in large markets:* Our goal is to create a robust pipeline of innovative, best-in-class therapeutics that capitalize upon the unique advantages of our TransCon technology. We intend to develop new TransCon-based product candidates in multi-billion dollar markets where we believe we can meaningfully improve the existing standard of care. We have initiated preclinical development efforts in the field of osteoarthritis, and are focused on identifying new opportunities characterized by high unmet medical need and with a high probability of clinical, regulatory and commercial success.
- *Continue to establish strategic collaborations with market-leading biopharmaceutical companies:* We intend to enter into additional collaborations with market-leading biopharmaceutical companies to develop and commercialize products in therapeutic categories of strategic importance to our collaborators. We will seek opportunities to structure our collaborations in ways that allow us to retain development and commercialization rights in key specialty markets where we can maintain a focused sales force. We expect our collaborations to provide substantial up-front technology licensing fees, development milestone payments and/or royalties, and reimburse us for the time we spend assisting them with research and development activities. This reduces our dependence on the financial markets to fund on-going operations and our development programs.
- *Pursue expedited regulatory pathways:* We intend to pursue the fastest feasible pathways to approval for our portfolio of product candidates. Because our TransCon technology enables the sustained release of an unmodified parent drug with established clinical safety, efficacy and tolerability, we believe, in many cases, that we will be in a position to pursue an expedited clinical development and regulatory approval pathway as compared to the development of traditional new molecular entities. These may include the Section 505(b)(2) approval pathway in the United States and similar pathways in non-U.S. markets, which pathway allows us to rely in part on studies of safety and effectiveness that were not conducted by us or on our behalf.
- *Strengthen our leadership position in the field of long-acting prodrug technology:* We believe that our deep experience base in developing TransCon-based product candidates establishes us as the leader in long-acting prodrug technology, and we intend to further strengthen this leadership position through investment in our TransCon technology, new technologies, our lab, clinical and commercial scale manufacturing capabilities and our methods and know-how. In partnership with our collaborators, we have developed a powerful and integrated set of capabilities that are critical to our ability to rapidly and efficiently develop, optimize and scale-up manufacturing for new TransCon-based product candidates. In addition, each of our collaboration partners has granted us rights that enable us to freely commercialize all improvements to the TransCon technology developed by our collaboration partners outside of the field identified in their respective collaboration agreements.

TransCon Technology

Overview: Prodrugs and Technologies to Extend Drug Exposure

Many drugs suffer from suboptimal pharmacokinetics, short residence time in the body, poor tolerability at the administration site and/or systemic side effects that result from initial drug concentrations that are too high. Frequent administration and poor tolerability negatively impact patient compliance and may lead to suboptimal treatment outcomes. To address these issues, several approaches are currently applied to improve drug characteristics, such as prodrug and sustained release technologies.

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

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

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

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

Our TransCon Technology

Our TransCon technology is designed to solve the fundamental limitations of previous approaches applied to extend duration of a drug's action in the body, and to enhance the overall benefit of a given therapeutic. Our TransCon technology establishes a new paradigm that combines the benefits of conventional prodrug and sustained release technologies, and is broadly applicable to proteins, peptides and small molecules. TransCon prodrugs predictably release unmodified active parent drugs and may offer advantages that include superior efficacy, safety, tolerability and compliance, including less frequent dosing and the ability to switch patients to subcutaneous injections from burdensome continuous infusions and less frequent dosing.

Our TransCon technology is differentiated in that it enables us to design long-acting prodrugs that predictably release an unmodified active parent drug at predetermined rates governed only by physiological pH and temperature conditions. Because these conditions are tightly regulated in the body, we are able to design our TransCon prodrugs to predictably release an unmodified active parent drug over an extended period of time without the risk of an initial burst release. 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.

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Advantages of our TransCon technology

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

Efficacy

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

Safety and Tolerability

- Same mode of action as parent drug
- Minimizes injection site reactions
- Enables switch from continuous infusions to daily or less frequent subcutaneous injections
- Offers low immunogenicity

Development and Regulatory

- Higher development success rate when incorporating approved parent drug
- May qualify for expedited approval pathways if based on approved parent drugs

Intellectual Property

- New composition of matter patents

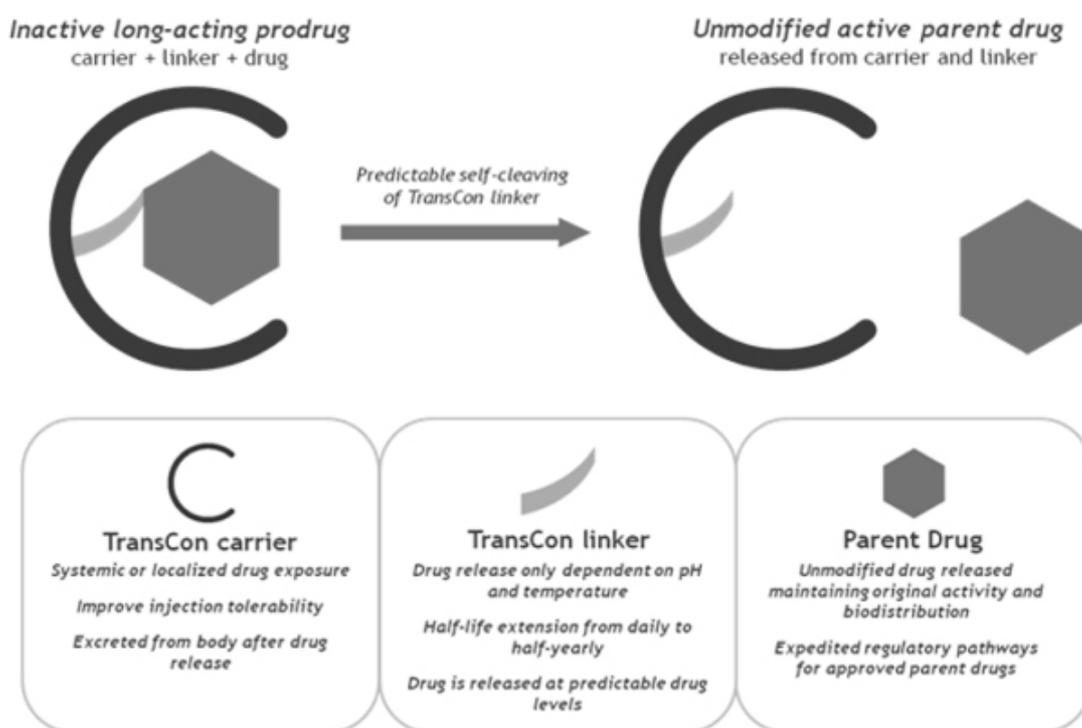
Technology Overview

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

Our TransCon carriers can be selected from our soluble or hydrogel carrier platforms. These carriers inactivate and protect the parent drug through a shielding effect, which prevents rapid excretion and degradation of the parent drug. The parent drug is connected to the carrier via the TransCon linker, which is designed to release the drug at a predictable and predetermined rate, enabling release of unmodified active parent drug with up to half-yearly administration. After drug release, the linker remains permanently attached to the carrier.

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Our broad selection of TransCon linkers, in combination with our soluble carriers and microparticle carriers, provides us with a powerful and flexible technology that we leverage to design best-in-class therapeutics aimed at multi-billion dollar markets. The broad applicability of the TransCon technology is reflected by the fact that our pipeline contains long-acting prodrugs incorporating proteins, peptides and small molecules.



TransCon Linkers

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

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TransCon Carriers

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

- Our TransCon soluble carriers are used for providing systemic drug exposure and are based on soluble compounds such as polyethylene glycol, or PEG, or other natural or synthetic polymers. Prodrugs created using our soluble carriers are readily absorbed into the bloodstream after administration, thus minimizing exposure of the subcutaneous tissue to active drug, which we believe may improve injection site tolerability. Our most advanced product candidates, TransCon hGH and TransCon Trepotstinil, utilize PEG as a carrier molecule. PEG is widely used to alter the pharmacokinetic or pharmacodynamic properties of marketed therapeutics.
- Our TransCon hydrogel carriers are being developed to provide either localized or systemic drug exposure. Our proprietary TransCon hydrogel is designed to be biocompatible and self-eliminating, and consists of microparticles that allow for highly efficient drug loading into the hydrogel via our TransCon linkers. The TransCon hydrogel is pre-formed and subsequently loaded with the parent drug, which can prevent adverse modification of the drug during manufacturing of the hydrogel. This process is proprietary, and we believe our granted patents prevent our competitors from creating prodrugs based on preformed hydrogels. Our current TransCon hydrogels are PEG-based and we are developing hydrogels based on hyaluronic acid and other biopolymers. Our TransCon hydrogel is designed to self-eliminate as small, well-defined and biocompatible molecules after the drug payload has been released. We and our collaboration partners are developing the TransCon hydrogel in both systemic and localized drug delivery applications. For example, our TransCon hydrogel is being utilized by Sanofi for systemic delivery in the TransCon Insulin program, and we use hydrogel for localized delivery in our TransCon osteoarthritis program.

Parent drug

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

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

TransCon Product Candidates

TransCon human Growth Hormone (hGH)

Our most advanced product candidate is TransCon human Growth Hormone, or TransCon hGH, for the treatment of growth hormone deficiency, or GHD. Leading products for the treatment of GHD require that patients, the

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majority of whom are children, receive daily injections over many years. The burden of daily administration often results in poor patient compliance and can lead to suboptimal treatment outcomes. Despite this, global annual sales from currently marketed hGH products grew to over \$3 billion in 2013 according to MedTRACK. We are developing TransCon hGH as a prodrug with once-weekly administration that releases unmodified growth hormone, maintaining the same mode of action as daily hGH therapies. Clinical studies of TransCon hGH have demonstrated a comparable efficacy, safety, tolerability and immunogenic profile to that of daily growth hormone. If approved, TransCon hGH may reduce the burden of daily treatment by requiring significantly fewer injections, which may improve compliance and treatment outcomes. We have successfully completed a Phase 2 study of TransCon hGH in adults with GHD and are currently enrolling children with GHD in a six-month Phase 2 study. In this Phase 2 study, we will be measuring height velocity, an efficacy measure that refers to the mean height change of the individuals in a group over a specified time period. In October 2014, we expect to report three-month data, including height velocity, from 50% of the patients in our Phase 2 pediatric study, and top-line data for all patients in the trial in the first half of 2015.

Overview of Growth Hormone Deficiency

GHD is a serious orphan disease that affects both children and adults. Children with GHD are characterized by short stature, metabolic abnormalities, cognitive deficiencies and poor quality of life. GHD in adults is associated with premature mortality, increased adiposity, or fat mass, as well as psychiatric-cognitive, cardiovascular, muscular, metabolic and skeletal abnormalities. hGH is used for the long-term treatment of children and adults that fail to secrete adequate amounts of endogenous growth hormone. Primary indications for hGH in children are GHD, idiopathic short stature, kidney disease, Prader-Willi Syndrome and Turner's syndrome. In adults, primary indications for hGH include GHD and AIDS-induced weight loss.

The use of recombinant hGH, or rhGH, was introduced in 1981, and since then many of the world's largest pharmaceutical companies have developed and now market daily growth hormone injections. Since the 1990s, the pharmaceutical industry has employed various approaches to develop long-acting growth hormone products to reduce the patient burden of daily injections and increase patient compliance with the dosing regimen. To date, regulatory agencies have approved only two long-acting growth hormone products, each of which utilize unmodified growth hormone as the active drug substance. Neither of these products has achieved commercial success, due to manufacturing, regulatory, efficacy safety and/or tolerability reasons.

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

- Height velocity: First-year height velocity of 10-12 cm
- Safety: Safe and well-tolerated
- Injection: Essentially pain free, <1.0 mL per injection
- Metabolic effects: Reduced adiposity and improved cardiovascular health
- Quality of life: Improved
- Device: Convenient and easy to use

Market Opportunity

According to MedTRACK, global annual sales from currently marketed daily hGH injections grew to over \$3 billion in 2013. We believe a significant market opportunity exists for a long-acting version of hGH with comparable efficacy, safety and tolerability as daily growth hormone products.

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The current standard of care for GHD is daily subcutaneous injections of rhGH. All currently marketed rhGH 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.), Tev-Tropin® (Teva Pharmaceuticals) and Omnitrope® (Sandoz GmbH), contain unmodified hGH and are administered by daily subcutaneous injections.

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

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

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

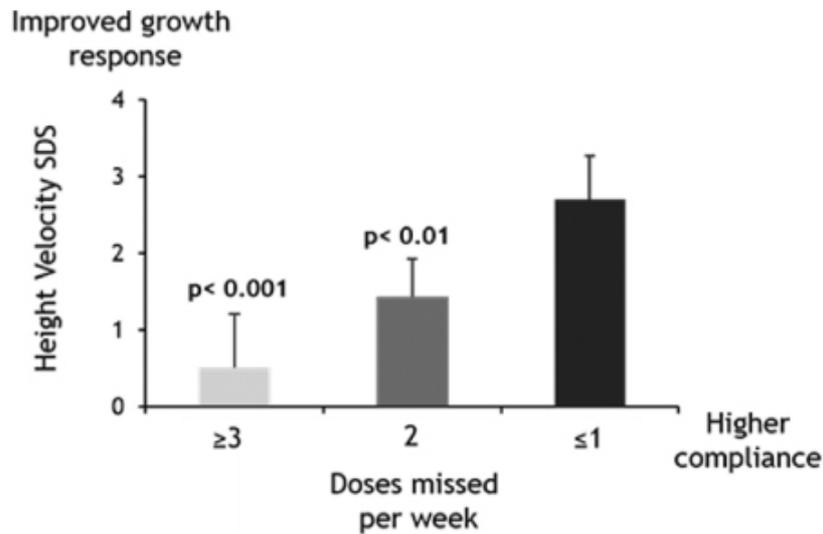


Figure 1. Negative impact of poor compliance on growth response.

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

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

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Encapsulation technologies

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

Modified growth hormone analogs

Modification technologies prolong growth hormone activity in the body by creating analogs of growth hormone through permanent modification of the growth hormone molecule. This modification may alter the molecular size and interaction with the growth hormone receptor and/ or change the natural association affinity to endogenous proteins, thereby reducing the body's ability to excrete the analog. We believe that these changes may alter the mode of action and distribution of modified growth hormone analogs into key growth hormone responsive tissues, such as brain, bone, muscle and fat, compared to unmodified growth hormone. These changes may alter and reduce the efficacy of these drugs compared to unmodified daily growth hormone and may also negatively impact the drug's safety. For instance, a modified growth hormone previously being developed by Pfizer was discontinued due to lipoatrophy, a condition of localized loss of fat tissue that can cause undesirable skin deformations, at the injection site following repeated administration in adult patients with GHD. Published data from clinical studies of modified growth hormone analogues demonstrate that growth hormone levels exceed normal physiological concentration following administration. Due to the risk of adverse effects, such as tumor proliferation, regulatory agencies have expressed concern regarding growth hormone levels, or the resulting IGF-I levels, exceeding physiological concentrations.

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

Ambrx, Inc., GeneScience Pharmaceuticals Co., Ltd., Hanmi Pharmaceutical, Novo Nordisk A/S, OPKO Health, Inc., Teva Pharmaceutical Industries Ltd. and Versartis, Inc. are developing long-acting growth hormone analogs based on permanent modification of growth hormone.

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

Our Solution: TransCon hGH

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

TransCon hGH is inactive when administered. This improves injection site tolerability compared to other long-acting growth hormone products. Full activity of the parent growth hormone is restored when unmodified growth hormone is released from the prodrug. As long as the growth hormone is in the prodrug form, elimination from the body is minimized, ensuring a long half-life. The TransCon linker releases the unmodified growth hormone in a self-cleaving process that relies only on physiological pH and temperature conditions, ensuring the predictable release of growth hormone and enabling a once-weekly dosing regimen.

We have conducted biopotency assays and generated mass spectrometry profiles demonstrating that the bioactivity and structure of growth hormone released from TransCon hGH is identical to the growth hormone in marketed growth hormone products administered as daily injections. As such, we expect our once-weekly TransCon hGH to have the same mode of action and distribution into key growth hormone-responsive tissues, such as brain, bone, muscle, liver and fat tissue, as the hGH administered from daily injections and endogenous growth hormone. We use daily growth hormone as an active comparator in our clinical studies, allowing us to directly compare the activity of TransCon hGH to daily growth hormone in an identical clinical setting.

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

Clinical Development of Once-weekly TransCon hGH

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

As shown below, IGF-I profiles following a single subcutaneous administration of TransCon hGH show a linear dose-response and are supportive of weekly dosing. The study demonstrated a comparable IGF-I response, the primary biomarker of growth hormone efficacy, following a single administration of TransCon hGH versus seven daily injections of hGH, at comparable dose.

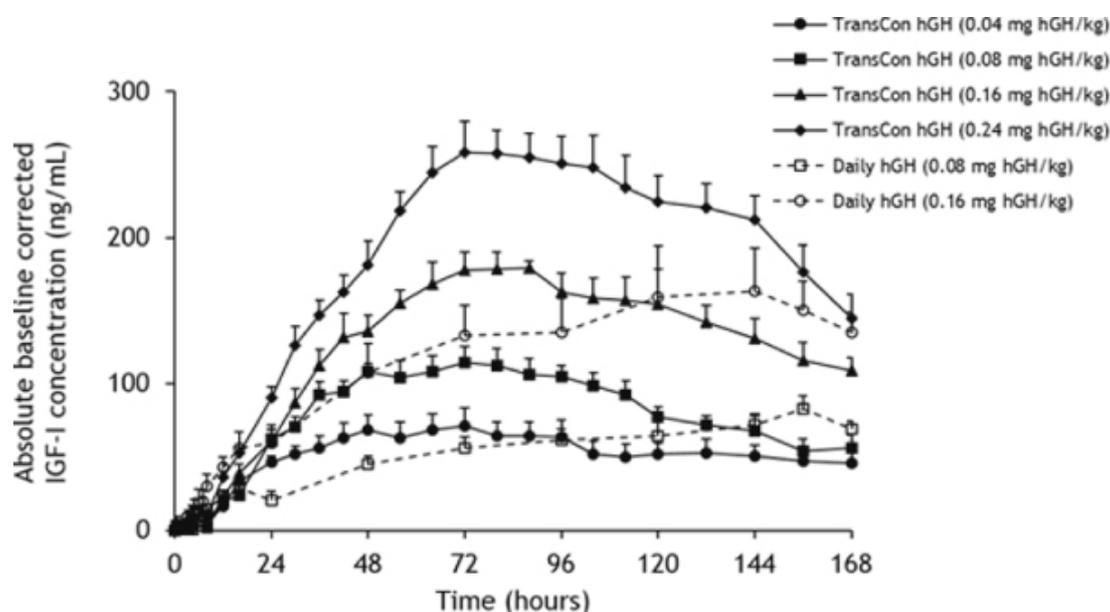


Figure 2. Phase 1 study in healthy adult male volunteers; n=7 and 4 for TransCon hGH and daily hGH dose groups, respectively; Error bars + Standard Error of the Mean.

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In June 2012, we conducted a Phase 1 single-dose study of TransCon hGH for once-weekly administration in healthy adult male and female volunteers, testing dose levels up to 0.36 mg hGH/kg/week. We believe this study supports a favorable safety profile for higher doses in the adult population and provides the foundation for evaluating higher doses in pediatric studies.

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

We have demonstrated that serum levels of free hGH and TransCon hGH increase proportionally with the administered dose. The maximum serum concentration of hGH released from TransCon hGH was comparable to the levels achieved by the corresponding amount of hGH given as daily injections. Figure 3 shows that the hGH profiles during Week 4 following weekly subcutaneous administration of TransCon hGH or daily subcutaneous administration of Omnitrope® (0.006 mg hGH/kg/day, equivalent to 0.04 mg hGH/kg/week) demonstrates good dose proportionality between TransCon hGH dose groups, with peak serum concentrations of hGH being comparable between dose matched TransCon hGH and daily hGH dose groups (0.04 mg hGH/kg/week).

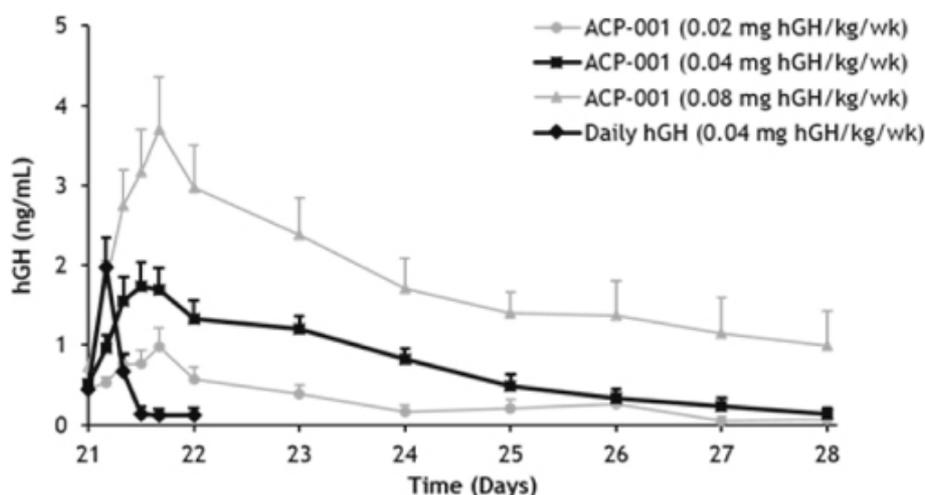


Figure 3. Phase 2 study in male and female adults with GHD; $n=10$ and 9 for TransCon hGH 0.02 / 0.04 mg hGH/kg/week and 0.08 mg hGH/kg/week dose groups, respectively and $n=8$ for the daily hGH (0.04 mg hGH/kg/week) dose group; Error bars +Standard Error of the Mean.

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

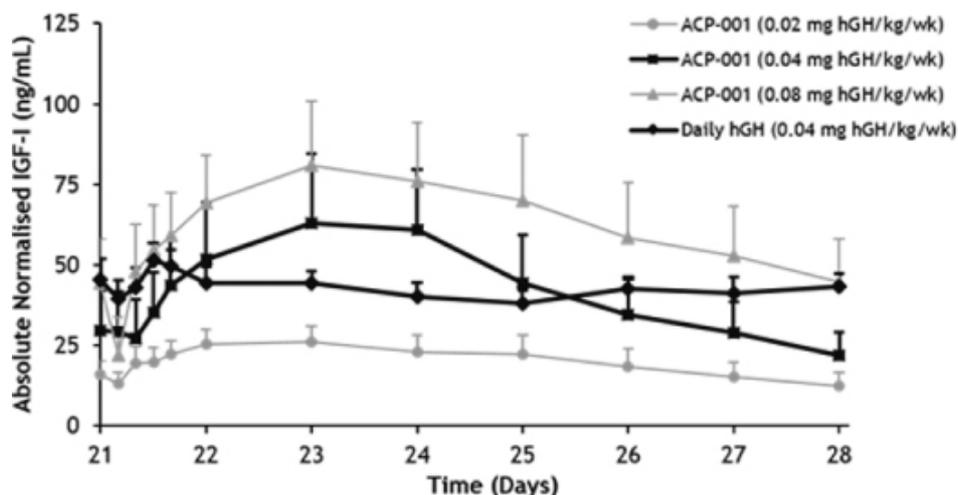


Figure 4. Phase 2 study in male and female adults with GHD; n=10 and 9 for TransCon hGH 0.02 / 0.04 mg hGH/kg/week and 0.08 mg hGH/kg/week dose groups, respectively and n=8 for the daily hGH (0.04 mg hGH/kg/week) dose group; Absolute baseline correction relative to Week 1 pre-dose IGF-I concentrations; Error bars +Standard Error of the Mean.

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

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

Phase 2 Study in Pediatric GHD

In September 2013, we initiated a Phase 2 pediatric clinical study to investigate safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of TransCon hGH in 52 treatment-naïve pre-pubertal patients with GHD. We are currently enrolling children who meet internationally recognized criteria for GHD. These include short stature as measured by height and height velocity, two hGH stimulation tests, a bone age evaluation and IGF-I levels below -1 standard deviation. The study is a multi-center, randomized, multiple-dose study comparing three dose-levels of once-weekly TransCon hGH to daily growth hormone treatment over a period of six months and we are enrolling patients in Europe and North Africa. We will compare 0.14 mg hGH/kg/week; 0.21 mg hGH/kg/week; and 0.30 mg hGH/kg/week to daily injections of Genotropin® at 0.03 mg hGH/kg/day, a cumulative dose equivalent to the mid-dose of TransCon hGH of 0.21 mg hGH/kg/week. The main efficacy endpoint is height velocity at six months. In October 2014, we expect to report three-month data, including height velocity, from 50% of the patients in our Phase 2 pediatric study, and top-line data for all patients in the trial in the first half of 2015.

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Development Plans

After the receipt of the data from our on-going Phase 2 study in pediatric patients, we intend to meet with the FDA and the European Medicines Agency, or EMA, to discuss the design of a Phase 3 clinical program. We plan to propose a single trial with a non-inferiority design compared to daily hGH with a primary endpoint of 12 month mean height velocity, with a non-inferiority margin similar to values used to achieve recent approval of daily growth hormone therapies, e.g., Omnitrope®. We believe the Phase 3 clinical program will consist of a single multicenter, open-label non-inferiority study comparing the safety and efficacy of once-weekly TransCon hGH to daily hGH in children with growth failure due to GHD. We expect the study will consist of approximately 150 treatment naïve, pre-pubertal growth hormone deficient children using inclusion criteria that are similar to those we employed in our Phase 2 pediatric clinical study.

We are also developing a high-strength formulation of TransCon hGH, which we refer to as ACP-011, that may be suitable for patients that require higher doses of growth hormone, including Turners Syndrome patients. This formulation is identical to our TransCon hGH product currently in Phase 2 development, with the exception that it incorporates a smaller PEG carrier molecule. The high-strength formulation is currently in preclinical development. We plan to use existing clinical data generated on our TransCon hGH product to support development of the high-strength formulation based on demonstration of comparable pharmacokinetics and pharmacodynamics. In addition, we are developing a state-of-the-art pen device with Bang & Olufsen Medicom A/S. This device is designed to be easy-to-use in the pediatric population and leverages proven technologies.

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

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

TransCon Treprostinil

We are developing TransCon Treprostinil for the treatment of PAH, a life-threatening disease characterized by elevated blood pressure in the pulmonary arteries. According to MedTRACK, the worldwide market for PAH therapies exceeded \$4 billion in 2013.

Treprostinil, the active agent in United Therapeutics' product Remodulin®, is the leading infused therapy for the treatment of PAH. We are applying our TransCon technology to develop TransCon Treprostinil to be given as a once-daily injection rather than as continuously infused therapy. This improvement in the administration of treprostinil is expected to minimize the limitations of infused treprostinil therapy, such as infusion site pain and the risk of infection. In June 2014, the FDA accepted an IND for TransCon Treprostinil.

Overview of Pulmonary Arterial Hypertension

PAH is a life-threatening disease characterized by elevated blood pressure in the pulmonary arteries. As the disease worsens, the right side of the heart works harder to pump blood to the lungs and this eventually leads to right heart failure and, ultimately, death. Treatments for PAH aim to reduce symptoms, improve quality of life and slow disease progression. In many cases, improvement in a patient's exercise capacity, as measured by the 6 minute walk distance test, is used as an indicator of therapeutic effect.

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Mild-to-moderately affected PAH patients can frequently be managed with oral therapies such as PDE-5 inhibitors and endothelin receptor antagonists. Oral or inhaled prostacyclin analog therapy may be added as symptoms worsen. Patients suffering from severe PAH may receive continuously infused prostacyclin analog therapies.

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

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

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

Market Opportunity

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

Limitations of Current Prostacyclin Therapies

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

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

Conventional Infused Prostacyclin Analog Therapy

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

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

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

Inhaled Prostacyclin Analogs

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

Oral Prostacyclin Receptor Agonists

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

Implantable Infusion Pump

United Therapeutics is supporting studies of treprostinil administered by an implantable pump, in partnership with Medtronic. The SynchroMed II Remodulin® pump will be surgically implanted in the abdomen of patients and re-filled by transdermal injection into an injection port. As the pump requires surgery for implantation, it is an invasive intervention and risks associated with the implantation surgery in an already fragile PAH patient base may affect adoption rates.

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Our Solution: TransCon Treprostinil

Our TransCon Treprostinil is designed to be a once-daily self-administered subcutaneous injection of treprostinil, intended to offer the same efficacy as continuously-infused prostacyclin analogs, but with a safer and more convenient route of administration, without the infusion site pain/reaction and bloodstream infection risks associated with the continuous subcutaneous and intravenous routes of administration of treprostinil, respectively.

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

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

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

Development of TransCon Treprostinil

In September 2012, we entered into a collaboration agreement with United Therapeutics under which we granted United Therapeutics a license to research, develop, make and commercialize products based on the TransCon technology and prostacyclin analogs, and later expanded the license to include the drug beraprost. In May 2014, United Therapeutics filed an IND for TransCon Treprostinil, which was subsequently accepted by the FDA in June 2014. On June 30, 2014, we received a notice from United Therapeutics informing us of its intent to terminate the collaboration agreement for convenience, and we are in the process of negotiating the transition of the program back to us.

As TransCon Treprostinil is a prodrug of treprostinil, we believe that we are eligible to pursue a Section 505(b)(2) regulatory strategy and rely upon the FDA's previous findings of safety and effectiveness for treprostinil. Depending upon the outcome of initial Phase 1 studies, we may further propose to the FDA that we pursue a Section 505(b)(2) regulatory strategy based on demonstrating bioequivalence of TransCon Treprostinil to Remodulin[®]. If the FDA agrees to our proposed Section 505(b)(2) regulatory path, the development timelines for TransCon Treprostinil may be expedited compared to conventional drug approvals.

TransCon Insulin

Overview

Together with our collaboration partner, Sanofi, we are developing TransCon Insulin for the treatment of diabetes, a major cause of morbidity and mortality across the world. The current standard of care for diabetes often includes daily insulin injections. Compliance and adherence to insulin regimens are poor due to the burden of daily injections. Failure to receive adequate and consistent levels of insulin leads to severe complications and even mortality in diabetic patients.

Market Opportunity

According to the WHO, diabetes is a global epidemic with 347 million people worldwide having diabetes. The basal insulin market alone exceeds \$7.5 billion and is expected to increase due in part to increasing obesity rates, according to MedTRACK.

Limitations of Current Basal Insulin Therapies

Efforts to improve patient adherence and avoid complications with insulin-based therapeutics have generally been based on creating longer acting insulin products as well as device and drug delivery innovations. Subcutaneous and percutaneous pumps are often used to deliver consistent levels of insulin, avoiding the variable plasma levels associated with daily injections. Other products contain insulin analogs that provide for slower absorption after subcutaneous injection. However, marketed basal insulin products are all administered as once-daily injections or continuous infusions.

Our Solution: TransCon Insulin

To improve treatment outcomes for diabetics, we have developed a once-weekly TransCon Insulin prodrug. Our long-acting TransCon Insulin is based on our TransCon hydrogel technology, and consists of human insulin covalently bound *via* slow-release TransCon linkers to a self-eliminating TransCon hydrogel. As the TransCon linker cleaves, insulin is liberated at safe and efficacious levels throughout the week. Because of the predictable nature of drug release from TransCon prodrugs, no burst release of insulin is observed in animal studies, reducing the risk of hypoglycemia. The TransCon technology is also applicable as an enabling platform for other anti-diabetic peptides and is ideally suited for fixed-dose combination therapies. TransCon Insulin is compatible with current insulin pen devices and fine needles, ensuring minimal discomfort upon administration.

Animal Data

As illustrated in Figure 5, in diabetic animal models, TransCon Insulin provides sustained insulin release and normalization of blood glucose for more than two weeks. TransCon Insulin was demonstrated to maintain glucose levels in the normal range throughout the week and to reach peak plasma insulin concentration within hours without generating a potentially life threatening burst release of insulin.

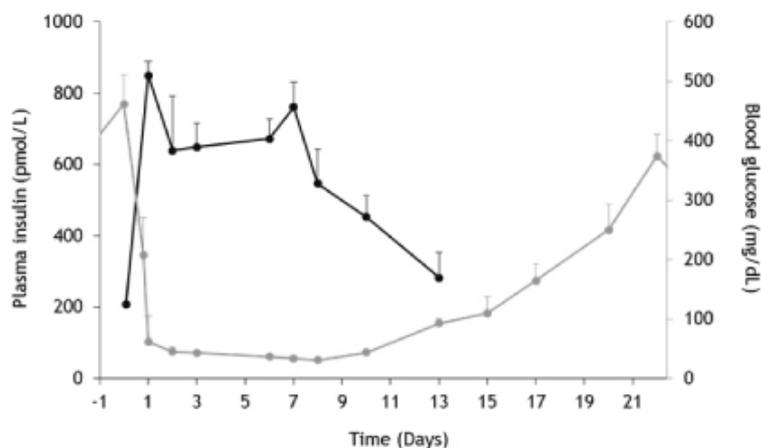


Figure 5. TransCon Insulin was administered as a single dose in a diabetic rat model, streptozotocin-treated rats, dose=24 mg/kg, n=8. Insulin release and normalization of blood glucose was observed for more than two weeks.

Development Plans

Our collaboration partner, Sanofi, has informed us that it has completed preclinical safety studies. Sanofi has also informed us that they are evaluating additional peptides in conjunction with the TransCon technology in the field of diabetes.

Strategic Collaboration with Sanofi

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

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the first application for marketing approval is for diabetes in humans in a major country. This license will become exclusive, on a peptide-by-peptide basis, for any licensed product containing a peptide that is non-proprietary to Sanofi and is designated by Sanofi if certain specified conditions are met. Under the agreement, Sanofi has granted us a non-exclusive, royalty-free license (with the right to grant sublicenses) under Sanofi's rights in any improvements generated in connection with the collaboration, to research, develop, make or commercialize products outside the scope of the collaboration and outside the field of diabetes.

In consideration for these licenses to the TransCon technology and as payment for the assignment of specific diabetes-related product patents, Sanofi provided 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 fixed payments upon Sanofi's achievement of specified clinical development and regulatory approval milestones and a specified payment amount 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. We may terminate the agreement upon 30 days' prior written notice if Sanofi fails to remit any undisputed sum it must pay to us. Each party may terminate the agreement upon 60 days' prior written notice for the other party's uncured material breach. Sanofi has the right to terminate the agreement in its entirety for convenience upon 90 days' prior written notice. Either party may terminate the agreement by written notice to the other party if the other party institutes a lawsuit or proceeding alleging non-infringement, invalidity or unenforceability with respect to any patent licensed to such other party under the agreement. Upon any such termination by us or by Sanofi for convenience, all licenses granted to Sanofi would terminate and, if such termination is by Sanofi for convenience prior to IND approval of a product under the agreement, we may require Sanofi to assign back to us the assigned patent rights upon payment of a specified amount.

TransCon Ranibizumab

Overview and Market Opportunity

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

In 2013, the worldwide sales of anti-VEGF ophthalmology drugs exceeded \$5 billion, comprised primarily of Lucentis® and a recent entrant Eylea® from Regeneron Pharmaceuticals, Inc./Bayer AG. There is high interest in developing longer acting therapies for intravitreal drug delivery in order to reduce the burdensome intravitreal injections required by the current standard of care. In this market, patient compliance remains a challenge and patients and physicians sometimes accept less than optimal dosing frequencies for certain individuals. A reliable and consistent method to achieve visual gains with up to half-yearly dosing represents a potential major breakthrough and could quickly become the new standard of care.

Limitations of Established Long-acting Anti-VEGF Technologies

Several types of drug-eluting ocular implants are approved in the United States, ranging from biodegradable inserts to non-biodegradable reservoirs. Non-biodegradable implants must be removed after a period of time

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requiring an additional invasive procedure. Biodegradable systems do not require removal, but are generally associated with erratic drug release and burst release.

Our Solution: TransCon Ranibizumab

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

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

Development Plans

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

Strategic Collaboration with Genentech

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

In consideration for these licenses, Genentech paid us a non-refundable up-front technology license fee of \$20 million (€15 million), and we are eligible to receive milestone payments upon Genentech's achievement of specified development milestones for all licensed products Genentech develops under the agreement, and upon the first commercial sale of these products in various markets. We are also eligible to receive tiered royalties on net sales of all products commercialized under the agreement at percentages ranging from the mid-single digits to the low double digits, subject to customary reductions and offsets. Genentech also provides funding for our research and development activities under an agreed-upon plan.

The term of the agreement expires on a product-by-product and country-by-country basis upon expiration of Genentech's obligation to pay us royalties on the net sales of licensed products, which extends until the later of a

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

TransCon Candidates for Osteoarthritis

Osteoarthritis affects over 27 million people in the United States alone, and it is estimated that osteoarthritis accounts for over \$185 billion in annual healthcare expenditure. It is difficult to achieve effective drug levels in the knee with systemic treatments, such as tablets, and current technologies to inject therapies into the knee suffer from short residence times within the knee. As a result current drugs are either ineffective, provide a therapeutic effect that is short lived and/or are associated with systemic side effects.

We are applying our TransCon technology to a series of active parent drugs to assess their ability to be administered on an up to half-yearly basis and to provide long term pain reduction and modify disease. In 2014 we anticipate initiating the manufacture of material of our lead candidate for use in toxicology studies, and we anticipate initiating the manufacturing of material for use on a second candidate in 2015.

Overview

Osteoarthritis is a painful, progressive, degenerative disorder of the joints. The primary pathophysiological characteristics of osteoarthritis are destruction of joint cartilage, inflammation of the synovial membrane lining joints and consequent swelling of the affected joint. These changes produce symptoms including severe pain, joint stiffness and loss of function. Many osteoarthritis patients progress to intractable joint pain, debilitating disease and eventually total joint replacement. Therefore, controlling pain, slowing down disease progression, and delaying the time to joint replacement surgery are key therapeutic goals.

Market Opportunity

The Centers for Disease Control and Prevention, or CDC, estimates that nearly 50% of individuals will develop symptomatic knee osteoarthritis by the age of 85 and that osteoarthritis afflicts approximately 27 million people in the United States with prevalence expected to increase to 67 million people by 2030. The osteoarthritis market continues to expand due to longer life spans, higher obesity rates, and the absence of disease-modifying drugs. It is estimated that osteoarthritis accounts for over \$185 billion in annual healthcare expenditure.

Limitations of Current Osteoarthritis Therapies

Physicians typically treat osteoarthritis based on disease severity and symptoms. Paracetamol and non-steroidal anti-inflammatory drugs, or NSAIDs, are widely prescribed for the treatment of pain in osteoarthritis. However, long-term use of oral NSAIDs can put patients at risk for cardiovascular issues or gastrointestinal bleeding. Oral NSAIDs do not provide adequate pain relief and patients frequently progress to require intra-articular injectable therapy.

Intra-articular injections of corticosteroids reduce the associated inflammation and pain, but are rarely used as first-line treatment as their effect is short-lived. Hyaluronic acid and related viscosupplementation products are

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widely used, and represent a \$1 billion market, but their efficacy is largely anecdotal and comparable to placebo effects in well-controlled clinical trials. Recently, the American Academy of Orthopedic Surgeons published guidance in which it could not recommend the use of hyaluronic acid because of lack of efficacy.

Current clinical guidelines limit the number of intra-articular injections patients can receive per year due to the invasive nature of the procedure. There is consequently a clear need for new long-acting therapeutic agents that reduce the pain and inflammation associated with osteoarthritis.

Our Solution: TransCon Technology

We are focused on developing a pipeline of long-acting intra-articular depots of drugs with proven analgesic and disease-modifying effects in osteoarthritis. The TransCon hydrogel delivery platform enables predictable drug release within the joint, ensuring high local concentrations with minimal systemic exposure, reducing the risk of systemic adverse effects. In animal models of osteoarthritis we have demonstrated that our TransCon hydrogel is highly biocompatible, that we can obtain significant half-life extension of a parent drug within the knee joint, and that we may slow disease progression following intra-articular injection of TransCon candidates.

We have demonstrated significant half-extension of TransCon Steroid injected intra-articularly in a rabbit model of knee osteoarthritis. The figure below illustrates plasma levels of the steroid released from the TransCon intra-articular depot, with a calculated half-life of approximately 45 days. In contrast, the plasma half-life following intra-articular injection of the steroid without our TransCon technology is approximately four hours.

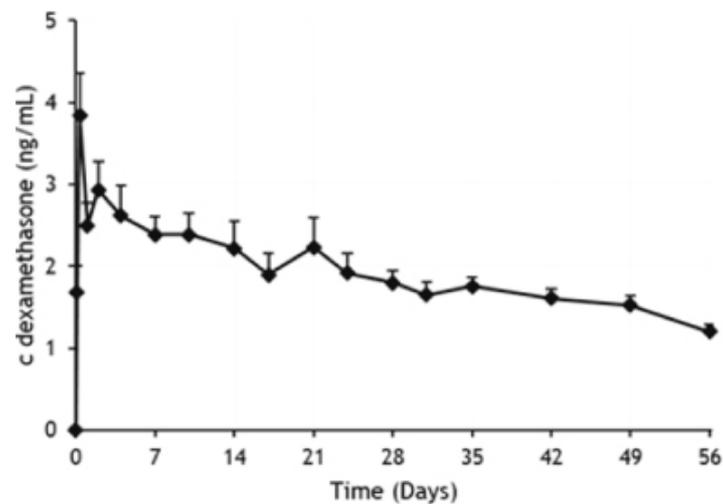


Figure 6. Plasma levels of a steroid, dexamethasone, after a single intra-articular injection in a rabbit model of osteoarthritis.

We have also demonstrated that TransCon Hydrogel prodrugs can alter disease progression in a rabbit model of knee osteoarthritis. In this study, rabbits were treated with a single intra-articular injection of either saline, TransCon Hydrogel steroid, or TransCon Hydrogel IL-1 inhibitor, or interleukin-1 inhibitor. Disease progression was assessed using standard methods, including analysis of joint space narrowing in the affected knee, providing

industry-standard Kellgren-Lawrence scores. Figure 7 illustrates the statistically significant improvement in Kellgren-Lawrence score for rabbits treated with either TransCon Steroid or TransCon IL-1 inhibitor:

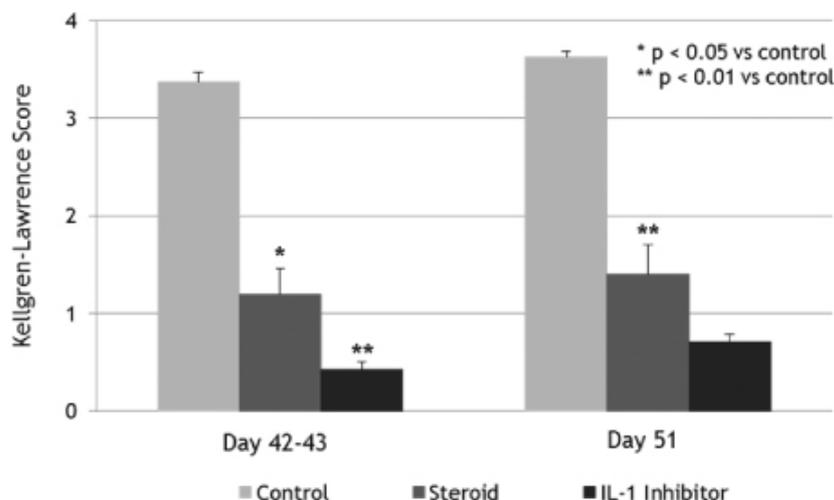


Figure 7. Rabbits with osteoarthritis were treated with a single intra-articular injection of TransCon prodrugs incorporating either a steroid or IL-1 inhibitor. At days 42, 43, and 51 rabbit knees were examined using state-of-the-art radiographic analyses and Kellgren-Lawrence scores were recorded. A decrease in Kellgren-Lawrence score indicates improvement in osteoarthritis disease progression. *p value < 0.05, **p value < 0.01, versus control.

These data confirm the ability of TransCon hydrogel to deliver drugs directly to tissues and cells in joints affected by osteoarthritis. The half-life achieved in the rabbit pharmacokinetic study depicted in the figure above supports a product profile with quarterly up to half-yearly administration.

Development Plans

TransCon candidates for osteoarthritis are being evaluated in preclinical models to assess their ability to provide long term pain reduction and to modify disease. In 2014, we anticipate initiating the manufacture of material of our lead candidate for use in toxicology studies, and we anticipate initiating the manufacturing of material for use on a second candidate in 2015. We currently retain worldwide commercial rights to all TransCon candidates for osteoarthritis.

Competition

The pharmaceutical industry is very competitive and subject to rapid and significant innovation. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies, universities, and other research institutions. Many of our competitors have greater resources, as well as larger research and development staff and more experienced marketing and manufacturing organizations. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are superior to, or more effectively marketed than, the product candidates that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive. For additional information regarding the companies that may be competitive with our product candidates currently in development see the descriptions of our current product candidates included above under the caption "TransCon Product Candidates."

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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 agency approvals and commence commercial sale of their drugs before their competitors may achieve a significant competitive advantage. Drugs resulting from our research and development efforts or from our joint efforts with collaboration partners therefore may not be commercially competitive with our competitors' existing products or products under development.

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

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 enforceable patents and proprietary rights of third parties. For more information, please see "Risk factors—Risks related to our intellectual property and information technology."

As of June 30, 2014, we own a total of 35 patent families, of which 12 are currently in their priority year or international phase and we own several granted patents in the United States (5), Europe (2), Australia (5), Canada (1), China (3), Israel (2), New Zealand (2), Japan (3) and South Africa (5) and have more than 160 pending national/regional applications in a total of 19 jurisdictions (excluding the member states of the European Patent Convention in which the EP patents were validated). We currently do not rely on licenses to any third party's intellectual property.

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

We own 21 technology patent families of which some or all were licensed to our collaboration partners, wherein each license is exclusive for a particular therapeutic field. In addition, one of our collaboration partners has exclusive licenses to two product-specific patent families. We have sold four insulin-/exendin-specific patent families to Sanofi.

We aim to protect our product candidates by building multiple layers of intellectual property around them. Our patent portfolio related to our TransCon hGH prodrug, for example, includes four different patent families relating to different aspects of the prodrug, namely the particular stoichiometry of drug and TransCon carrier, the TransCon linker, a broad class of TransCon hGH lead candidate structures and to specific dry pharmaceutical compositions comprising such prodrugs. The earliest of these patents is expected to expire in 2024, the last in 2030.

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In the field of diabetes, our patent portfolio related to our TransCon prodrugs under development with our collaboration partner Sanofi include the four product-specific patent families sold to them and four technology patents owned by us, namely a patent family broadly directed to the TransCon linker, two patent families relating to the TransCon hydrogel and one patent family relating to the sterilization of TransCon hydrogel. Patents granted from these patent families are expected to expire in 2029, 2025, 2030 and 2030, respectively.

Our patent portfolio related to our work in the ocular field includes two product-specific patent families exclusively licensed to our collaboration partner, one patent family relating to the TransCon linker used, two patent families relating to the TransCon hydrogel, one patent family relating to the sterilization of the TransCon hydrogel and one patent family directed to inventions useful in the synthesis of the relevant prodrugs. Patents granted from these patent families are expected to expire between 2025 and 2034.

Our patent portfolio related to TransCon Trepstinil currently includes two patent families, one aiming at broadly protecting the product concept and the other relating to the actual lead candidate structure. Patents granted from these patent families are expected to expire in 2032.

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

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

Manufacturing

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

We have analytical and process development capabilities in our own facility. We generally perform synthesis of our proprietary drug candidate development, analytical and process development for our proprietary drug candidate internally and manufacture the drugs necessary to conduct the non-GLP preclinical studies of our investigational product candidates. We occasionally outsource the production of research and development

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material. Occasionally our collaboration partners may conduct production of research and development material for products in their respective field. Each of our collaboration partners have granted us rights that enable us to freely commercialize all improvements to the TransCon Prodrug technology and manufacturing process developed by our collaboration partners outside of the field identified in their respective collaboration agreements.

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

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

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

Government Regulation and Product Approval

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

U.S. Government Regulation

In the United States, we are subject to extensive regulation by the FDA, which regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations, and other federal, state, and local

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regulatory agencies. The FDCA and its implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

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

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

Preclinical Studies

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

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any

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subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their www.clinicaltrials.gov website.

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

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

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

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Marketing Approval

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

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

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

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

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

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

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

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

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an

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

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

Post-Approval Requirements

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

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

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

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

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;

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

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

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

Hatch-Waxman Amendments and Exclusivity

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

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

If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired. Specifically, the holder of the

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NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by FDA in any other NDA. An “active moiety” is defined as the molecule or ion responsible for the drug substance’s physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA’s findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

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

Pediatric Exclusivity

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

Foreign Regulation

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

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

Centralized Procedure

The centralized procedure provides for the grant of a single marketing authorization from the European Commission following a favorable opinion by the Committee for Medicinal Products for Human Use, or the

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

National Authorization Procedures

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

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

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

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

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

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

Other Healthcare Laws

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

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

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

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

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

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

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other

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

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

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

Coverage and Reimbursement

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

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

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness

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of drug products and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

Healthcare Reform

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

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

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

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

Employees

As of June 30, 2014, we employed 53 full-time employees, 43 of whom hold a Ph.D., M.D., or equivalent degrees. Of the full-time employees, 45 were engaged in research and development and 8 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.

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Property and Facilities

Our headquarters are located at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark, where we lease approximately 1,469 square feet of office space. The lease for our headquarters expires on October 31, 2015. We maintain a research facility in Heidelberg, Germany, where we lease 16,095 square feet of office and laboratory space. The lease for our Heidelberg facility expires January 31, 2017. We have also leased 300 square feet of office space in Palo Alto, California pursuant to a lease that expires January 31, 2015. 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.

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.

Corporate Organization

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) in December 2007. We commenced operations in December 2007 in connection with the acquisition of the company that invented our TransCon technology, Complex Biosystems GmbH. Certain of our operations are conducted through our subsidiaries and we have the following subsidiaries Ascendis Pharma GmbH (Germany), Ascendis Pharma, Inc. (Delaware, United States), Ascendis Pharma, Ophthalmology Division A/S (Denmark), Ascendis Pharma, Growth Disorders Division A/S (Denmark), Ascendis Pharma, Osteoarthritis Division A/S (Denmark) and Ascendis Pharma, Circulatory Diseases Division A/S (Denmark). Our principal executive offices are located at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark and our telephone number is +45 36 94 44 86.

MANAGEMENT

General

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, as well as a brief summary of certain significant provisions of Danish corporate law and the articles of association that will be in effect upon the closing of this offering, which relate to our board of directors and executive board.

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

Board of Directors

The following table sets forth information with respect to each of our board members and their respective ages as of June 30, 2014. The terms of office of all our board members expire at the next annual general meeting to be held in 2015. All board members are eligible for re-election.

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

<u>Name of Board Member</u>	<u>Age</u>	<u>Position(s)</u>
Jan Møller Mikkelsen	55	President, Chief Executive Officer, Board Member and Executive Director
Michael Wolff Jensen, L.L.M.	42	Chairman and Senior Vice President, General Counsel
Rafaèle Tordjman, M.D., Ph.D.	45	Board Member
Edwin de Graaf	43	Board Member
Michael Mayer	60	Board Member
Martin Olin	45	Board Member

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

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

Edwin de Graaf has served as a member of our board of directors since June 2014. Since July 2006, Mr. de Graaf has served as a Managing Partner of Gilde Healthcare Partners B.V., a European venture capital firm. From 1998 to 2006, Mr. de Graaf served as an Investment Director of Gilde. Mr. de Graaf currently serves as a member of the board of directors for several privately held biotechnology companies. Mr. de Graaf received a Master's of Business and Fiscal Economics from the Erasmus University Rotterdam, the Netherlands.

Michael Mayer has served as a member of our board of directors since December 2007. Mr. Mayer founded TechnoStart, a venture capital firm specializing in early-stage technology investments and has served as a Managing Partner since 1990. Prior to starting TechnoStart, Mr. Mayer headed the technology transfer group at Fraunhofer-Institute for Systems and Innovation Research. Mr. Mayer received a Masters in Economics from the University of Konstanz in Germany.

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

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 June 30, 2014. In addition to serving as members of our senior management, Mr. Mikkelsen and Mr. Soloway 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.

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Jan Møller Mikkelsen	55	President, Chief Executive Officer, Board Member and Executive Director
Michael Wolff Jensen, L.L.M.	42	Chairman and Senior Vice President, General Counsel
Thomas P. Soloway	47	Senior Vice President, Chief Financial Officer and Executive Director
Harald Rau, Ph.D.	44	Senior Vice President, Chief Scientific Officer
Grethe Rasmussen, Ph.D.	52	Senior Vice President, Product Development
Lotte Sønderbjerg	53	Senior Vice President, Chief Administrative Officer
Martin Auster, M.D.	39	Senior Vice President, Chief Business Officer
Peter Rasmussen	45	Vice President, Finance and Principal Accounting Officer

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

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

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

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Thomas P. Soloway joined Ascendis Pharma in January 2014 as our Senior Vice President, Chief Financial Officer. Prior to Ascendis Pharma, Mr. Soloway held various positions at Transcept Pharmaceuticals, Inc., a publicly traded biotechnology company, including Senior Vice President, Operations and Chief Financial Officer from February 2009 to April 2012 and Executive Vice President and Chief Operating Officer from April 2012 to December 2013. Prior to the completion of a merger between Transcept and Novacea, Inc., Mr. Soloway served as Chief Financial Officer of Transcept since 2003, and as the Senior Vice President, Operations and Chief Financial Officer of Transcept since 2005. Prior to joining Transcept, from 1993 to 2002, Mr. Soloway worked with Montreux Equity Partners, a venture capital firm, in the development, structuring and financing of early stage healthcare and life sciences companies. Mr. Soloway received a B.S. in Entrepreneurial Studies from the University of Southern California and an M.B.A. from Georgetown University.

Harald Rau, Ph.D. has served as our Senior Vice President, Chief Scientific Officer, managing the research group at Ascendis Pharma since December 2007. Prior to Ascendis Pharma, Dr. Rau served as the Chief Scientific Officer of Complex Biosystems GmbH, a biotechnology company Dr. Rau co-founded in 2002, which was acquired by Ascendis Pharma in December 2007. Prior to co-founding Complex Biosystems, Dr. Rau, built and led the chemical technology development group at Graffinity Pharmaceuticals AG, a biotechnology company, from 1998 to 2002. Dr. Rau received a Ph.D. from the University of Freiburg.

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

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

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

Peter Rasmussen joined our company in March 2014 as Vice President, Finance and Principal Accounting Officer. 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.

Corporate Governance

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 or prevent 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 members of our board of directors are elected for a term of one year and may be re-elected. 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, as amended, which have been filed as an exhibit to the registration statement of which this prospectus forms a part.

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.

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.

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Committees of the Board of Directors

Upon the closing of this offering, we will 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

Upon the closing of this offering, our audit committee will consist of _____ (Chairman), _____ and _____. Each member satisfies the independence requirements of the NASDAQ listing standards, and _____ 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 will oversee our accounting and financial reporting processes and the audits of our consolidated financial statements. Our Audit committee meets all of the relevant criteria for independence under NASDAQ rule 5615. Our audit committee will be 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

Upon the closing of this offering, our remuneration committee will consist of _____ (Chairman), _____ and _____. Each member satisfies the independence requirements of the NASDAQ listing standards. Our remuneration committee will assist 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. Our remuneration committee will be 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

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- 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

Upon the closing of this offering, our nominating and corporate governance committee will consist of (Chairman), and . Each member satisfies the independence requirements of the NASDAQ listing standards. Our nominating and corporate governance committee will assist 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 will be 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.

Code of Business Conduct and 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. Following the closing of this offering, the code of business conduct and ethics will be available on our website at www.ascendispharma.com. We expect that any amendments to the code, or any waivers of its requirements, will be disclosed on our website. The information on, or that can be accessed through, our website is not part of and should not be incorporated by reference into this prospectus.

Other Corporate Governance Matters

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. 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 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.

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

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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.

Compensation

Compensation of Members of Our Board of Directors and Senior Management

Only William Ringo, a former member of our board of directors, and Mr. Jensen received compensation for their services as board members during the fiscal year ended December 31, 2013. Board members who were employees of our company or affiliated with our principal shareholders did not receive any compensation for their services on our board of directors. The aggregate compensation paid to Messrs. Ringo and Jensen for their board service was €85,226, consisting of: (i) board fees (cash) of €45,479, and (ii) share-based payments of €39,747. Share-based payments reflect the 2013 expenses of warrants granted in or before 2013. During 2013, Mr. Jensen also received fees of €19,429 for consulting services performed for our company. In June 2013, Mr. Jensen joined our company as general counsel, after which no board or consulting fees were paid to Mr. Jensen.

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

The aggregate compensation paid to our senior management who were employed by our company during 2013, consisting of Messrs. Mikkelsen and Jensen, Ms. Sønderbjerg and Drs. Rasmussen and Rau, for the fiscal year ended December 31, 2013 was €1.9 million. This amount consists of: (i) short-term employee benefits including salary and other in-kind benefits of €1.2 million, (ii) bonuses of €0.2 million, (iii) share-based payments of €0.4 million, and (iv) post-employment benefits of €1,200. Share-based payments reflect the 2013 expenses of warrants granted in or before 2013. During 2013, our board granted 14,772 warrants to Mr. Jensen with an exercise price of €31.9847 and expiration date of August 21, 2023. No other equity awards were granted to our senior management or our board members during 2013.

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, 2013 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 Mr. Jensen, Ms. Sønderbjerg and Dr. Rasmussen contain a termination notice period of three months for a termination by the employee and six months for a termination by us (except that in the case of Ms. Sønderbjerg and Dr. Rasmussen, the notice period may be no less than the notice required pursuant to the

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rules of the Danish Salaried Employees Act with addition of two months). The agreement with Dr. Rau contains a termination notice period of six months for a termination by the employee or by us (other than in the case of a termination for good cause which does not require notice). The employment agreements with Messrs. Soloway and Auster provide that in the event of nonrenewal of their respective employment agreements, a termination without cause by us or a termination for good reason by the employee, each will be entitled to six months' continued salary and benefits. Messrs. Soloway and Auster are also entitled to 12 months continued salary and benefits where such termination occurs as a result of or within 12 months following an initial public offering. The agreements with certain of our senior management contain post-termination non-competition covenants that generally may last for a period of 12 months post-termination and entitle the executives to their base salary, or portion thereof, during the period.

Warrant Incentive Program

Our employees, consultants, advisors and board members are eligible to participate in our warrant incentive program. Warrants are issued by the board pursuant to valid authorizations in our articles of association. The terms and conditions of the warrants have, in accordance with applicable Danish laws and regulations, been incorporated into our articles of association. 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. Following this offering, our board will be authorized to issue an additional _____ warrants through _____, 2019.

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 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 since December 2012 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.

Following the closing of this offering, vested warrants may be exercised in two annual exercise periods that run for 21 days from and including the day after the publication of (i) the annual report notification—or if such notification is not published—the annual report and (ii) the interim report (six-month report). With respect to 295,952 warrants granted prior to the last exercise period following 21 days from the publication of the interim report, there will be an additional 21-day exercise. For all other warrants, the last exercise period is 21 days following the publication of the interim report for the first half of 2023.

For further information regarding our warrant incentive program, see "Description of Share Capital—Our Warrants" and our articles of association which have been filed as an exhibit to the registration statement of which this prospectus forms a part.

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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 June 30, 2014. Dr. Tordjman, and Messrs. de Graaf and Mayer, who may be deemed to beneficially own more than 1% of our outstanding ordinary shares, did not hold any warrants as of June 30, 2014.

<u>Name</u>	<u>Grant Date</u>	<u>Awards granted and outstanding</u>	<u>Awards granted and outstanding, but unvested as of June 30, 2014</u>	<u>Award Exercise Price(s)</u>	<u>Award Expiration Date</u>
Jan Møller Mikkelsen	December 3, 2012	79,843	49,902	€31.9847	August 21, 2023
Harald Rau, Ph.D.	September 10, 2008	30,350	—	€10.5930	August 21, 2015
	March 19, 2009	15,104	—	€10.5930	August 21, 2015
	December 3, 2012	44,132	25,744	€31.9847	August 21, 2023
Michael Wolff Jensen	September 10, 2008	11,363	—	€10.5930	August 21, 2015
	December 9, 2009	11,364	—	€10.5930	August 21, 2015
	December 3, 2012	6,818	4,261	€31.9847	August 21, 2023
	June 27, 2013	14,772	11,079	€31.9847	August 21, 2023

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 intend to enter into agreements with our board members and members of our senior management, pursuant to which, subject to limited exceptions, we will 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.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of related party transactions we have entered into since January 1, 2011 with any of our board members, our senior management and the owners of more than five percent of our share capital.

Sales and Subscriptions for Securities

Issuance of Preference C Shares Pursuant to Conversion of Convertible Debt

In May 2011, we issued an aggregate of 174,097 preference C shares at €31.984727 per share. All of those shares were issued in exchange for conversion of our convertible debt payable on May 31, 2011, pursuant to a convertible loan, dated June 30, 2010, as amended on March 30, 2011. The aggregate gross consideration received for these issuances was €5,568,440.

The table below sets forth the number of preference C shares in exchange for conversion of debt, and the aggregate subscription price of the preference C shares issued to the members of our board of directors, senior management and the owners of more than five percent of a class of our share capital, or an affiliate or immediate family member thereof:

<u>Name</u>	<u>Number of Shares of Preference C Shares in Exchange for Conversion of Debt</u>	<u>Aggregate Subscription Price (€)</u>
Sofinnova Capital V FCPR ⁽¹⁾	93,778	2,999,461
Gilde Healthcare II Sub-Holding B.V. ⁽²⁾	54,764	1,751,615
Partnership Zweite TechnoStart Ventures Fonds GmbH & Co. KG i.L. ⁽³⁾	25,555	817,364

(1) Rafaële Tordjman, M.D., Ph.D., a member of our board of directors, is a managing partner of Sofinnova Partners.

(2) Edwin de Graaf, a member of our board of directors, is a managing partner of Gilde Management.

(3) Michael Mayer, a member of our board of directors, is a managing director of TechnoStart.

Shareholders' Agreement

We entered into a shareholders' agreement with the holders of our preference C shares, preference B shares, and ordinary A shares, including entities with which certain members of our board of directors are affiliated. As of June 30, 2014, the holders of 2,700,487 of our ordinary shares, including the ordinary shares following the conversion of our preference B and preference C shares, are entitled to rights with respect to the registration of their shares under the Securities Act. The shareholders' agreement also provides for a right of first refusal in favor of our shareholders. The shareholders' agreement also provides for the right of certain holders of preference C shares to elect certain members of our board of directors. The shareholders' agreement and all of the rights therein will terminate upon the closing of this offering.

Employment Agreement and Warrant Grants

We have entered into employment agreement with, and issued warrants to, the members of our senior management. See "Management—Compensation" and "Management—Warrant Incentive Program" for more information.

Indemnification Agreements

We intend to enter into indemnification agreements with our board members and the members of our senior management. See "Management—Insurance and Indemnification" for a description of these indemnification agreements.

PRINCIPAL SHAREHOLDERS

The following table sets forth information relating to the beneficial ownership of our shares as of June 30, 2014, 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 June 30, 2014 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 2,700,487 ordinary shares outstanding as of June 30, 2014, which reflects the assumed conversion of all of our preference shares and ordinary A shares. Ordinary shares that a person has the right to subscribe for within 60 days of June 30, 2014 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. 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	Beneficial Ownership Prior to this Offering				Beneficial Ownership After this Offering	
	Number of Outstanding Shares Beneficially Owned	Number of Warrants Exercisable Within 60 Days	Number of Shares Beneficially Owned	Percentage of Beneficial Ownership	Number of Shares Beneficially Owned	Percentage of Beneficial Ownership
5% and Greater Shareholders						
Sofinnova Capital V FCPR ⁽¹⁾	1,221,459	—	1,221,459	45.2%		
Gilde Healthcare II Sub-Holding B.V. ⁽²⁾	714,784	—	714,784	26.5%		
Zweite TechnoStart Ventures Fonds GmbH & Co. KG i.L. ⁽³⁾	440,819	—	440,819	16.3%		
Dirk Vetter ⁽⁴⁾	120,930	45,454	166,384	6.1%		
Board Members and Senior Management						
Jan Møller Mikkelsen ⁽⁵⁾	159,685	33,268	192,953	7.1%		
Harald Rau, Ph.D. ⁽⁶⁾	42,810	65,681	108,491	3.9%		
Michael Wolff Jensen ⁽⁷⁾	—	29,876	29,876	1.1%		
Grethe Rasmussen, Ph.D. ⁽⁸⁾	—	25,568	25,568	*		
Lotte Sønderbjerg ⁽⁹⁾	—	25,568	25,568	*		
Thomas P. Soloway ⁽¹⁰⁾	—	4,761	4,761	*		
Martin Auster, M.D. ⁽¹¹⁾	—	1,360	1,360	*		
Peter Rasmussen ⁽¹²⁾	—	729	729	*		
Rafaèle Tordjman, M.D., Ph.D. ⁽¹⁾	1,221,459	—	1,221,459	45.2%		
Edwin de Graaf ⁽²⁾	714,784	—	714,784	26.5%		
Michael Mayer ⁽³⁾	440,819	—	440,819	16.3%		
Martin Olin ⁽¹³⁾	—	265	265	*		

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

- (1) Consists of 1,221,459 ordinary shares following conversion of preference C shares held by Sofinnova Capital V FCPR. Sofinnova Partners SAS, a French corporation and the management company of Sofinnova Capital V FCPR, may be deemed to have sole voting and investment power, and the managing partners of Sofinnova Partners SAS, Dennis Lucquin, Antoine Papiernik, Dr. Tordjman and Monique Saulnier, may be deemed to have shared voting and investment power with respect to such shares. The address of Sofinnova Capital V FCPR is 16-18 Rue du Quatre-Septembre, 75002 Paris, France.
- (2) Consists of 714,784 ordinary shares following conversion of preference C shares held by Gilde Healthcare II Sub-Holding B.V., or Gilde Healthcare. The manager of Gilde Healthcare is Gilde Healthcare II Management B.V., or Gilde Management, and Gilde Management is owned by Gilde Healthcare Holding B.V., or Gilde Holding. Three managing partners, via their personal holding companies Manapouri B.V. (of which Edwin de Graaf is the owner and manager), Charlofix B.V. (of which Marc Olivier Perret is the owner and manager) and Martemanshurk B.V. (of which Pieter van der Meer is the owner and manager) each own interests in Gilde Holding and Stichting Administratiekantoor Gilde Healthcare Holding, or Stichting, owns interests in Gilde Holding. Stichting is controlled by Manapouri B.V., Charlofix B.V. and Martemanshurk B.V. and issued depository receipts for shares in Gilde Holding to Manapouri B.V., Charlofix B.V., Martemanshurk B.V. and Franken Ventures B.V. (of which Arthur Franken is owner and manager). Each of Mr. de Graaf, Mr. Perret and Mr. van der Meer share voting and dispositive power of the shares, and disclaim beneficial ownership of the shares except to the extent of their respective pecuniary interest therein. The address of Gilde Healthcare II Sub-Holding B.V. is Newtonlaan 91, 3584 BP, Utrecht, The Netherlands.
- (3) Consists of (i) 274,983 ordinary shares following conversion of preference B shares and (ii) 165,836 ordinary shares following conversion of preference C shares held by Zweite TechnoStart Ventures Fonds GmbH & Co. KG i.L., or TechnoStart. Mr. Mayer is the managing director of Zweite TechnoStart Ventures Verwaltungs GmbH, which is the general partner of TechnoStart, and as such Mr. Mayer exercises voting and dispositive control over the shares in Ascendis Pharma held by TechnoStart. The address of TechnoStart Ventures is Kernaeckerstr. 5, 71732 Tamm, Germany.
- (4) Consists of (i) 120,930 ordinary shares following conversion of ordinary A shares held by Mr. Vetter and (ii) 45,454 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of June 30, 2014 by Mr. Vetter.
- (5) Consists of (i) 159,685 ordinary shares following conversion of ordinary A shares held by Mr. Mikkelsen and (ii) 33,268 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of June 30, 2014 by Mr. Mikkelsen.
- (6) Consists of (i) 42,810 ordinary shares following conversion of ordinary A shares held by Dr. Rau and (ii) 65,681 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of June 30, 2014 by Dr. Rau.
- (7) Consists of 29,876 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of June 30, 2014 by Mr. Jensen.
- (8) Consists of 25,568 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of June 30, 2014 by Dr. Rasmussen.
- (9) Consists of 25,568 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of June 30, 2014 by Ms. Sønderbjerg.
- (10) Consists of 4,761 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of June 30, 2014 by Mr. Soloway.
- (11) Consists of 1,360 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of June 30, 2014 by Dr. Auster.
- (12) Consists of 438 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of June 30, 2014 by Mr. Rasmussen.
- (13) Consists of 265 ordinary shares that may be subscribed pursuant to the exercise of warrants within 60 days of June 30, 2014 by Mr. Olin.

DESCRIPTION OF SHARE CAPITAL**Introduction**

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 and relevant provisions of the Danish Companies Act. The summary includes certain references to and descriptions of material provisions of our articles of association and Danish law in force as of the date of this prospectus. The summary below contains only material information concerning our share capital and corporate status and does not purport to be complete and is qualified in its entirety by reference to our articles of association and applicable Danish law.

General

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

Development of the Share Capital

As of December 31, 2013 and as of June 30, 2014, our registered, issued and outstanding share capital was 2,700,487 divided into 323,425 ordinary A shares, 274,983 preference B shares and 2,102,079 preference C shares. In connection with the closing of this offering, all of our outstanding shares will be converted, on a one-for-one basis, to ordinary shares pursuant to a resolution by the general meeting. The development of our share capital since our inception is set forth in the table below.

<u>Date</u>	<u>Transaction</u>	<u>Share Capital After Transaction</u>	<u>Share Class after the Increase</u>	<u>Price Per Share (EUR)</u>
September 2006	Formation	125,000		0.14
November 2007	Cash contribution	159,685		0.14
December 2007	Cash contribution	1,517,508	323,425 ordinary A shares	10.5930
	Contribution in kind		274,983 preference B shares 919,100 preference C shares	
December 2008	Cash contribution	2,272,727	323,425 ordinary A shares 274,983 preference B shares 1,674,319 preference C shares	10.5930
June 2010	Debt conversion	2,526,390	323,425 ordinary A shares 274,983 preference B shares 1,927,982 preference C shares	10.5930
May 2011	Debt conversion	2,700,487	323,425 ordinary A shares 274,983 preference B shares 2,102,079 preference C shares	31.9847

In addition to the above, 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 _____ without pre-emptive subscription rights for our existing shareholders in connection with this offering.
- Following this offering, our board of directors will be authorized to increase our share capital by up to _____ without pre-emptive subscription rights for existing shareholders in connection with cash contributions, debt conversion and contributions in kind of up to _____ provided, however, that the capital increases are carried out at market value.

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- Following this offering, our board of directors will be authorized to increase our share capital by up to _____ with pre-emptive subscription rights for existing shareholders in connection with cash contributions, debt conversion and contributions in kind of up to _____.
- Following this offering, our board of directors will be authorized to issue _____ warrants and to increase our share capital by up to _____ 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.

The above authorizations are valid until _____, 2019. If our board of directors exercises its authorizations in full then our share capital will amount to _____ consisting of _____ shares with a nominal value of DKK 1 each, following this offering and assuming no exercise of the underwriters' option to subscribe for additional ordinary shares.

At the extraordinary general meeting held on _____, 2014, our board of directors was authorized to allow our company to acquire up to _____ % of our share capital as treasury shares at a price corresponding to +/- _____ %. The authorization is valid until _____, 2019. As of the date of this prospectus, we have not used this authorization.

Our Shares

We intend to apply to list our ordinary shares on The NASDAQ Global Market under the symbol “_____.”

All of our shares will, following closing of this offering, be ordinary shares. The shares issued in connection with this offering will rank *pari passu* with all other ordinary shares.

Our shares will be registered in electronic, non-certificated form with VP Securities A/S, our share registrar and transfer agent. Initial settlement of the ordinary shares offered in this offering is expected to take place on or about the closing date of this offering through The Depository Trust Company, or DTC, in accordance with its customary settlement procedures for equity securities. Accordingly, we will issue the ordinary shares issued in this offering by us in book-entry form in the name of Cede & Co., the nominee used by DTC.

Under Danish law, holders of beneficial interests in our ordinary shares in respect of which Cede & Co. is registered as nominee in our share register will not have the usual rights conferred on shareholders by our articles of association or the Danish Companies Act. For example, only directly registered shareholders may attend and vote at our annual general meeting of shareholders in person. Furthermore, since Cede & Co. will be registered as a nominee in our owners' register, Cede & Co. will not be able to exercise any of the administrative shareholder rights attaching to the shares without a proxy or power of attorney from beneficial owners. In addition, any dividends that such beneficial owners may be entitled to will be paid to Cede & Co. with full effect of discharge by the company.

If you subscribe for shares in this offering, you must look solely to your broker or bank for the payment of all dividends, the exercise of voting rights attaching to our ordinary shares and all other rights arising in respect of our ordinary shares. Your broker or bank must, in turn, look solely to DTC for the payment of all dividends, the exercise of voting rights attaching to our ordinary shares and all other rights arising with respect to our ordinary shares. If you decide to hold indirectly through your broker or bank and DTC, you must rely on the procedures of your broker or bank. Please consult with your broker or bank to determine those procedures. Because you will not be a registered shareholder of our company, you may look only to your broker or bank for recourse related to your beneficial interest in the shares.

In order to directly exercise administrative rights as a shareholder, you will need to have a directly registered position with our share registrar and transfer agent, or provide our share registrar and transfer agent with notice of your acquisition of, and good title to, your shares. You may request through your broker or bank to hold

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securities directly in registered form instead of holding securities indirectly through DTC. Your broker may obtain on your behalf shares in electronic form through VP Securities A/S, our share registrar and transfer agent. However, the conversion from a beneficial interest in securities held by Cede & Co. for DTC as nominee to directly registered securities, and vice versa, may require both time and the payment of processing fees to our share registrar and transfer agent, in addition to fees that may be levied by your broker or bank. If you elect to hold directly in registered form in your own name, you must first establish an account with VP Securities A/S, our share registrar and transfer agent. You will then be a registered shareholder of our company and therefore you may more easily be able to exercise the shareholder rights attaching to the shares than would be the case if you hold securities indirectly through DTC.

Our Warrants

We have established warrant programs for members of our board of directors, our senior management, other employees, consultants and advisors.

As of June 30, 2014, we have issued 613,225 warrants. Each warrant confers the right to subscribe for 1 ordinary share. Our warrants have been granted, on the dates, and with exercise prices as set forth below:

<u>Grant Date</u>	<u>Vesting Period</u>	<u>Expiration Date</u>	<u>Exercise Price</u>	<u>Number of Warrants</u>
September 10, 2008	24 - 36 months	August 21, 2015	€ 10.5930	155,970
March 19, 2009	24 -36 months	August 21, 2015	€ 10.5930	82,755
December 9, 2009	24 - 36 months	August 21, 2015	€ 10.5930	42,727
December 13, 2011	36 months	August 21, 2015	€ 31.9847	14,500
October 8, 2012	36 months	August 21, 2015	€ 31.9847	16,500
December 3, 2012	48 months	August 21, 2023	€ 31.9847	172,651
March 19, 2013	48 months	August 21, 2023	€ 31.9847	7,100
June 27, 2013	48 months	August 21, 2023	€ 31.9847	21,872
September 24, 2013	48 months	August 21, 2023	€ 31.9847	14,000
December 5, 2013	48 months	August 21, 2023	€ 31.9847	3,000
January 16, 2014	48 months	August 21, 2023	€ 31.9847	33,148
March 6, 2014	48 months	August 21, 2023	€ 31.9847	7,000
June 19, 2014	48 months	August 21, 2023	€ 31.9847	42,002

The weighted average subscription price per share per outstanding warrant is approximately €22.17 (\$30.25).

Vesting Principles Generally

All 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. The description below merely contains a summary of the applicable terms and conditions and does not purport to be complete. Warrants issued vest, in general, at a rate of 1/24th, 1/36th or 1/48th per month from the date of grant. Some warrants have, however, been deemed vested in part upon grant. Moreover, all warrants vest fully in the event that we are merged as the discontinuing company or demerged or if more than 50% of our share capital is sold or is part of a share swap. The warrants issued are subject to certain restrictions on exercise as further described below.

Vesting and Exercise Principles for the Senior Management and Employees

Warrants cease to vest upon termination of the warrant holder's employment relationship with us in the event that (i) a warrant holder resigns without this being due to our breach of contract or (ii) if we terminate the employment relationship with cause. In these instances the warrant holder will be entitled to exercise already vested warrants in the first exercise period after termination. If the first exercise period after termination falls within three months

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of the termination date, the warrant holder shall, additionally, be entitled to exercise in the following exercise period. In all other instances of termination, warrants continue to vest as they would normally have vested had the employee remained employed.

Vesting Principles for Board Members, Consultants and Advisors

Vesting of warrants issued to board members, consultants and advisors is conditional upon the warrant holder's continuous service as a board member, consultant or advisor, respectively.

Exercise Periods

Following the closing of this offering, vested warrants may be exercised in two annual exercise periods that run for 21 days from and including the day after the publication of (i) the annual report notification—or if such notification is not published—the annual report and (ii) the interim report (six-month report). With respect to 295,952 warrants granted prior to the last exercise period following 21 days from the publication of the interim report, there will be an additional 21-day exercise. For all other warrants, the last exercise period is 21 days following the publication of the interim report for the first half of 2023.

In the event of liquidation, a merger, a demerger or a sale or share exchange of more than 50% of our share capital, the warrant holders may be granted an extraordinary exercise period immediately prior to the transaction in which warrants may be exercised.

Adjustments

Warrant holders are entitled to an adjustment of the number of warrants issued and/or the exercise price applicable in the event of certain changes to our share capital at a price other than the market price and in the event of payments of dividends in a given year in excess of 10% of our equity capital. 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, and issuance of bonus shares.

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.

Owners' Register

We are obligated to maintain an owners' register (DK: *ejerbog*). The owners' register is maintained by VP Securities A/S. The ordinary shares offered in this offering will be held through DTC, and therefore DTC or its nominee will be recorded in the owners' register as the holder of the ordinary shares issued in this offering. It is mandatory that the owners' register is maintained within the European Union and that it is available to public authorities.

Articles of Association and Danish Corporate Law

At an extraordinary general meeting of shareholders held on _____, 2014, our shareholders resolved to amend our articles of association effective as of the closing of this offering. In connection with the closing of this offering the following resolutions will thus come into effect:

- all preference B shares and preference C shares will be reclassified into ordinary shares on a one-for-one basis;
- ordinary shares will remain ordinary shares, however, the denomination "A" will be deleted; and
- all shares will become non-certificated bearer shares.

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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. Board members are elected by the shareholders at the annual general meeting for a term of one year. Members of the board of directors may stand for re-election. Currently, the board of directors consists of six members who are elected by the shareholders. Board members must retire from the board of directors at the annual general meeting following their 70th birthday.

The board of directors shall appoint and employ an executive management consisting of one to three 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. 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.

Holders of beneficial interests in the ordinary shares held by Cede & Co. for DTC as nominee will be instructed by their broker or bank on how to exercise the voting rights for their ordinary shares. We have no legal obligation to mail to such beneficial owners any notice of our annual general meetings of shareholders. However, we may elect to provide either DTC, or the designee of DTC's participating brokerage (in the United States, generally Broadridge Financial Solutions, Inc.) materials related to such meetings and the related notices. In turn, the designee may distribute copies of materials related to such meetings or notices to you, if you are a holder of beneficial interests indirectly through DTC, through your broker or bank. You may instruct your broker or bank as to how you wish it to exercise the voting rights attached to the shares in which you hold beneficial interests. However, there may be practical and legal limitations in voting such shares. For example, only directly registered shareholders may attend and vote at our annual general meeting of shareholders in person. Your sole recourse for any voting matters will be to your broker or bank. See "Description of Share Capital—Our Shares" for more information.

Holders of shares directly registered with VP Securities A/S, our share registrar and transfer agent, will receive materials and notices of meeting directly from us or our designee. Voting materials must be submitted directly back to VP Securities A/S or as the voting materials otherwise require.

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, including subscribers of shares in this offering, are eligible to receive any dividends declared and paid out after the date of effectiveness of the registration statement of which this prospectus forms a part. 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

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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.

Our dividends, if declared, are paid in DKK to shareholders that are directly registered with VP Securities A/S, our share registrar and transfer agent. Holders of beneficial interests through DTC will receive any dividends through DTC; such dividends will be paid to Cede & Co., as nominee for DTC, with full effect of discharge by the company. There are no dividend restrictions or special procedures for non-resident holders of our shares. Dividends which have not been claimed within three years from the time they are payable are forfeited and all such dividends will accrue to our company.

See “Taxation” for a summary of certain tax consequences in respect of dividends or distributions to holders of our shares.

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 “Development of Share Capital”.

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.

Rights Attaching to the Shares

Upon the closing of this offering, all of our shares will have equal rights and rank.

Registration of Shares

All shares are held in book-entry form and must be held through DTC, a Danish bank or other institution authorized to be registered as the custodian of such shares on accounts maintained in the computer system of VP Securities A/S, our share registrar and transfer agent.

Limitations on Holding of Shares

There are no limitations on the right to hold shares under the articles of association or Danish law.

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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 or 90% 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.

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 three weeks' notice and a maximum of five 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.

At the latest, three 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. 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 is one week before the general meeting is held. Shares held by the individual shareholder are calculated on the registration date on the basis of the registration of ownership in our register of owners, as well as notifications concerning ownership which we have received. In addition, any shareholder who is entitled to attend a general meeting and who wishes to attend and vote in person must have requested an admission card from us no later than three days in advance of the general meeting. Shareholders who are entitled to vote may vote by letter. Votes made by letter must be received by us no later than noon on the business day before 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 a 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

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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 beneficial interests in the ordinary shares held by Cede & Co. for DTC as nominee are not entitled to directly receive notices or other materials, may not attend or vote at general meetings, and must follow any procedures set forth by their broker or bank with respect to exercising their voting or other administrative rights. See “—Voting Rights.”

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 the 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.

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.

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 listed 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 corporation law, including the Delaware General Corporation Law.

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

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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 in 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 one year. 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 suspend or dismiss a director by a simple majority vote.

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, new board members are elected by the shareholders in a general meeting also in the event of vacancies. A general meeting will thus have to be convened in order to fill a vacancy on the board of directors.

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.

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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 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 listed limited liability companies with bearer shares are convened by the board of directors with a minimum of three weeks' notice and a maximum of five weeks' notice (for unlisted companies with a notice of minimum two weeks and a maximum of four weeks) by announcement on the Danish Business Agency's IT Information System as well as on the company's webpage. 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. For each general meeting of shareholders, a record date will be applied with respect to ordinary shares in order to establish which shareholders are entitled to attend and vote at the general meeting of shareholders, which date is set forth in the articles of association. The record date and the manner in which shareholders can register and exercise their rights will be set out in the notice of the meeting.

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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 to redeem his or her shares. Similarly, a majority shareholder holding more than 90% of the company's share capital 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

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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 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 on name 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.

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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 “Development of Share Capital.”

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 under U.S. securities law.

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.

Under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, however, 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

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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.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our ordinary shares. Future sales of our ordinary shares, including shares issued upon the exercise of outstanding options or warrants, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our ordinary shares to fall or impair our ability to raise equity capital in the future. As described below, only a limited number of ordinary shares will be available for sale in the public market for a period of several months after closing of this offering due to contractual and legal restrictions on resale described below. Future sales of our ordinary shares in the public market either before (to the extent permitted) or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our ordinary shares at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sale of Restricted Shares

Based on the number of ordinary shares outstanding as of June 30, 2014 and assuming an initial public offering price of _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, upon the closing of this offering and assuming (1) the conversion of our outstanding convertible ordinary shares and preference shares into 2,700,487 ordinary shares, (2) no exercise of the underwriters' option to subscribe for additional ordinary shares to cover over-allotments, and (3) no exercise of any of our other outstanding warrants, we will have outstanding an aggregate of approximately _____ ordinary shares. Of these shares, all of the _____ ordinary shares to be sold in this offering, and any shares sold upon exercise of the underwriters' option to subscribe for additional ordinary shares to cover over-allotments, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144 of the Securities Act (subject to the terms of any lock-up agreements referred to below, if applicable). All remaining ordinary shares held by existing shareholders immediately prior to the closing of this offering will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Regulation S, Rule 144 or Rule 701, which rules are summarized below.

As a result of the lock-up agreements referred to below and the provisions of Regulation S, Rule 144 and Rule 701 under the Securities Act, based on the number of ordinary shares outstanding as of June 30, 2014 and assumptions (1) – (3) described above, the ordinary shares (excluding the shares sold in this offering) that will be available for sale in the public market are as follows:

<u>Approximate Number of ordinary Shares</u>	<u>First Date Available for Sale into Public Market</u>
shares	_____ days after the date of this prospectus upon expiration of the lock-up agreements referred to below, subject in some cases to applicable volume limitations under Rule 144

Lock-Up Agreements

In connection with this offering, we, our board members, our senior management and all of our other shareholders and warrant holders have agreed, subject to certain exceptions, with the underwriters not to dispose of or hedge any of our ordinary shares or securities convertible into or exchangeable for ordinary shares during the period from the date of the lock-up agreement continuing through the date _____ days after the date of this prospectus, except with the prior written consent of the underwriters.

Prior to the completion of the offering, certain of our employees, including our senior management and/or board members may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to this offering described above.

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Following the lock-up periods set forth in the agreements described above, and assuming that the underwriters do not release any parties from these agreements, all of the ordinary shares that are restricted securities or are held by our “affiliates” as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Rule 144

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our “affiliates” for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our “affiliates,” is entitled to sell those shares in the public market (subject to the lock-up agreement referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than “affiliates,” then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable). In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our “affiliates,” as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those ordinary shares that does not exceed the greater of:

- 1% of the number of ordinary shares then outstanding, which will equal approximately _____ ordinary shares immediately after this offering (calculated as of June 30, 2014 on the basis of assumptions (1) – (3) described above); or
- the average weekly trading volume of our ordinary shares on The NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our “affiliates” or persons selling shares on behalf of our “affiliates” are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired ordinary shares from us in connection with a written compensatory share or option plan or other written agreement in compliance with Rule 701 under the Securities Act before the effective date of the registration statement of which this prospectus is a part (to the extent such ordinary shares are not subject to a lock-up agreement) is entitled to rely on Rule 701 to resell such shares beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act in reliance on Rule 144, but without compliance with the holding period requirements contained in Rule 144. Accordingly, subject to any applicable lock-up agreements, beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act, under Rule 701 persons who are not our “affiliates,” as defined in Rule 144, may resell those shares without complying with the minimum holding period or public information requirements of Rule 144, and persons who are our “affiliates” may resell those shares without compliance with Rule 144’s minimum holding period requirements (subject to the terms of the lock-up agreement referred to above, if applicable).

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Regulation S

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act.

Incentive Plans

We intend to file with the SEC a registration statement under the Securities Act covering the ordinary shares that we may issue upon exercise of outstanding warrants reserved for issuance under our Warrant Incentive Program. Such registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

TAXATION

Danish Tax Considerations

The following is a summary of certain Danish income tax considerations relating to an investment in our 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 our shares. The summary is based solely on the tax laws of Denmark in effect on the date of this prospectus. 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 shares and further assumes that the direct investors are the beneficial owners of the shares and any dividends thereon. Sales are assumed to be sales to a third party.

Potential investors in our shares are advised to consult their tax advisors regarding the applicable tax consequences of acquiring, holding and disposing of the shares 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 Shareholders

Sale of Shares (Individuals)

Gains from the sale of shares are taxed as share income at a rate of 27% on the first DKK 49,200 in 2014 (for cohabiting spouses, a total of DKK 98,400) and at a rate of 42% on share income exceeding DKK 49,200 (for cohabiting spouses over DKK 98,400). 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).

For Danish tax purposes, shares admitted to trading on Nasdaq (US) are considered as shares admitted to trading on a regulated market. Gains and losses on the sale of shares admitted to trading on a regulated market are calculated as the difference between the purchase price and the sales price. The purchase price is generally determined using the average method as a proportionate part of the aggregate purchase price for all the shareholder's shares in the company.

Losses on the sale of shares admitted to trading on a regulated market can only be offset against other share income deriving from shares admitted to trading on a regulated market, (*i.e.*, received dividends and capital gains on the sale of shares admitted to trading on a regulated market). Unused losses will automatically be offset against a cohabiting spouse's share income deriving from shares admitted to trading on a regulated market and additional losses can be carried forward indefinitely and offset against future share income deriving from shares admitted to trading on a regulated market.

Losses on shares admitted to trading on a regulated market may only be set off against gains and dividends on other shares admitted to trading on a regulated market if the Danish tax authorities have received certain information concerning the ownership of the shares.

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Sale of Shares (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:

“*Subsidiary Shares*” is generally defined as shares owned by a shareholder holding at least 10% of the nominal share capital of the issuing company.

“*Group Shares*” is generally defined as shares in a company in which the shareholder of the company and the issuing company are subject to Danish joint taxation or fulfill the requirements for international joint taxation under Danish law (*i.e.*, the company is controlled by the shareholder).

“*Tax-Exempt Portfolio Shares*” is defined as shares not admitted to trading on a regulated market owned by a shareholder holding less than 10% of the nominal share capital of the issuing company.

“*Taxable Portfolio Shares*” is defined as shares that do not qualify as Subsidiary Shares, Group Shares or Tax-Exempt Portfolio Shares.

Gains or losses on disposal of Subsidiary Shares and Group Shares and Tax-Exempt Portfolio Shares are not included in the taxable income of the shareholder.

Special rules apply with respect to Subsidiary Shares and Group Shares in order to prevent exemption through certain holding company structures just as other anti-avoidance rules may apply. These rules will not be described in further detail.

Capital gains from the sale of Taxable Portfolio Shares admitted to trading on a regulated market are taxable at a rate of 24.5% (this rate is reduced to 23.5% in 2015 and 22% in 2016) 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 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.

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Dividends paid to individuals are generally subject to 27% withholding tax.

Dividends (Companies)

Dividends paid on both Tax-Exempt and Taxable Portfolio Shares are subject to the standard corporation tax rate of 24.5% (this rate is reduced to 23.5% in 2015 and 22% in 2016) irrespective of ownership period.

The withholding tax rate is 22%. A claim for repayment must be filed within two months. Otherwise, the excess tax will be offset in the corporation income tax for the year.

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

Taxation of Shareholders Residing Outside Denmark

Sale of Shares (Individuals and Companies)

Shareholders 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 that will not be described in further detail. If an investor holds the shares in connection with a trade or business conducted from a permanent establishment in Denmark, gains on shares may be included in the taxable income of such activities pursuant to the rules applying to Danish tax residents as described above.

Dividends (Individuals)

Under Danish law, dividends paid in respect of shares are generally subject to Danish withholding tax at a rate of 27%. Non-residents of Denmark are not subject to additional Danish income tax in respect to dividends received on shares.

If the withholding tax rate applied is higher than the applicable final tax rate for the shareholder, a request for a refund of Danish tax in excess hereof can be made by the shareholder in the following situations:

Double Taxation Treaty

In the event that the shareholder is a resident of a state with which Denmark has entered into a double taxation treaty, the shareholder may generally, through certain certification procedures, seek a refund from the Danish tax authorities of the tax withheld in excess of the applicable treaty rate, which is typically 15%. Denmark has entered into tax treaties with approximately 80 countries, including the United States, Switzerland and almost all members of the European Union. The treaty between Denmark and the United States generally provides for a 15% tax rate.

Credit Under Danish Tax Law

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

In addition, there is a special tax regime that applies to dividends distributed to individuals residing in certain countries, such as the United States, the United Kingdom, Belgium, Canada, Greece, the Netherlands, Ireland,

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Luxembourg, Norway, Switzerland, Sweden and Germany. This special tax regime provides that taxes on dividends may be withheld at the applicable tax rate specified in the relevant tax treaty. In order to qualify for the application of this special tax regime, an eligible holder of shares must deposit his shares with a Danish bank, and the shareholding must be registered with and administered through VP Securities A/S.

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

Dividends (Companies)

Dividends from Subsidiary Shares are exempt from Danish withholding tax provided the taxation of the dividends is to be waived or reduced in accordance with the Parent-Subsidiary Directive (2011/96/EEC) or in accordance with a tax treaty with the jurisdiction in which the company investor is resident. If Denmark is to reduce taxation of dividends to a foreign company under a tax treaty, Denmark will not—as a matter of domestic law—exercise such right and will in general not impose any tax at all. Further, dividends from Group Shares—not also being Subsidiary Shares—are exempt from Danish withholding tax provided the company investor is a resident of the European Union or the EEA and provided the taxation of dividends should have been waived or reduced in accordance with the Parent-Subsidiary Directive (2011/96/EEC) or in accordance with a tax treaty with the country in which the company investor is resident had the shares been Subsidiary Shares.

Dividend payments on both Tax-Exempt and Taxable Portfolio Shares will generally be subject to withholding tax at a rate of 27% irrespective of ownership period. If the withholding tax rate applied is higher than the applicable final tax rate for the shareholder, a request for a refund of Danish tax in excess hereof can be made by the shareholder in the following situations:

Double Taxation Treaty

In the event that the shareholder is a resident of a state with which Denmark has entered into a double taxation treaty, the shareholder may generally, through certain certification procedures, seek a refund from the Danish tax authorities of the tax withheld in excess of the applicable treaty rate, which is typically 15%. Denmark has entered into tax treaties with approximately 80 countries, including the United States and almost all members of the European Union. The treaty between Denmark and the United States generally provides for a 15% rate.

Credit under Danish Tax law

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

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

Share Transfer Tax and Stamp Duties

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

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

The following discussion describes the material U.S. federal income tax consequences to U.S. Holders (as defined below) under present law of an investment in our ordinary shares. The effects of any applicable state or local laws, or other U.S. federal tax laws such as estate and gift tax laws, or the Medicare contribution tax on net investment income, are not discussed. This summary applies only to investors who hold our ordinary shares 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 offering. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below.

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

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons whose functional currency is not the U.S. dollar;
- persons holding our ordinary shares as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities, commodities or currencies;
- partnerships, S corporations, or other entities or arrangements treated as partnerships for U.S. federal income tax purposes;
- tax-exempt organizations or governmental organizations;
- persons who acquired our ordinary shares pursuant to the exercise of any employee share option or otherwise as compensation;
- persons that own or are deemed to own 10% or more of our voting stock;
- persons that hold their shares through a permanent establishment or fixed base outside the United States; and
- persons deemed to sell our ordinary shares 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 OUR ORDINARY SHARES.

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

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or

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- a trust that (1) is subject to the supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

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

Passive Foreign Investment Company

Based on the value and composition of our assets, we may be a PFIC for U.S. federal income tax purposes for our current taxable year and future taxable years. 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 our ordinary shares, our PFIC status will depend in large part on the market price of our ordinary shares, which may fluctuate significantly. Based on our retention of a significant amount of cash and cash equivalents, and depending on the market price of our ordinary shares, we may be a PFIC for the current taxable year and future taxable years.

If we are a PFIC for any year during which you hold our ordinary shares, we generally will continue to be treated as a PFIC with respect to you for all succeeding years during which you hold our ordinary shares, unless we cease to be a PFIC and you make a “deemed sale” election with respect to the ordinary shares you hold. If such election is made, you will be deemed to have sold the ordinary shares 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 ordinary shares with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

For each taxable year we are treated as a PFIC with respect to you, you will be subject to special tax rules with respect to any “excess distribution” you receive and any gain you realize from a sale or other disposition (including a pledge) of our ordinary shares, 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 ordinary shares 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 our ordinary shares:

- the excess distribution or gain will be allocated ratably over your holding period for the ordinary shares,
- the amount allocated to the current taxable year, and any taxable year before the first taxable year in which we were a PFIC, will be treated as ordinary income, and

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- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years before the year of disposition or “excess distribution” cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of our ordinary shares cannot be treated as capital, even if you hold the ordinary shares 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 shares in such lower-tier PFICs that are directly or indirectly owned by us in the proportion that the value of the ordinary shares you own bears to the value of all of our ordinary shares, 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 our ordinary shares, 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 our ordinary shares as of the close of your taxable year over your adjusted basis in such ordinary shares. You are allowed a deduction for the excess, if any, of the adjusted basis of the ordinary shares 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 ordinary shares 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 ordinary shares, are treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any mark-to-market loss on the ordinary shares, as well as to any loss realized on the actual sale or disposition of the ordinary shares to the extent the amount of such loss does not exceed the net mark-to-market gains previously included for such ordinary shares. Your basis in the ordinary shares will be adjusted to reflect any such income or loss amounts. If you make a valid mark-to-market election, the tax rules that apply to distributions by corporations which are not PFICs would apply to distributions by us, except the lower applicable tax rate for qualified dividend income would not apply. If we cease to be a PFIC when you have a mark-to-market election in effect, gain or loss realized by you on the sale of our ordinary shares will be a capital gain or loss and taxed in the manner described below under “Taxation of Disposition of Our Ordinary Shares.”

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. We expect our ordinary shares will be listed on the NASDAQ and, accordingly, provided the ordinary shares are regularly traded, if you are a holder of ordinary shares, 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 ordinary shares cease to be marketable stock. If we are a PFIC for any year in which the U.S. Holder owns ordinary shares 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.

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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 IMPACT OF OUR POTENTIAL PFIC STATUS ON YOUR INVESTMENT IN OUR ORDINARY SHARES AS WELL AS THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN OUR ORDINARY SHARES.

Taxation of Dividends and Other Distributions on Our Ordinary Shares

Subject to the PFIC rules discussed above, the gross amount of any distribution to you with respect to our ordinary shares 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 ordinary shares, 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. As discussed above, we believe we may be a PFIC for our current taxable year and future taxable years. You should consult your tax advisor regarding the availability of this preferential tax rate under your particular circumstances.

As discussed in “Taxation,” 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 above, any tax withheld with respect to distributions on the ordinary shares 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.

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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 our ordinary shares generally will constitute “passive category income” or “general category income.” The rules with respect to the foreign tax credit are complex and involve the application of rules that depend upon a U.S. Holder’s particular circumstances. You are urged to consult your tax advisor regarding the availability of the foreign tax credit under your particular circumstances.

Taxation of Disposition of Our Ordinary Shares

Subject to the PFIC rules discussed above, you will recognize gain or loss on any sale, exchange or other taxable disposition of an ordinary share equal to the difference between the amount realized (in U.S. dollars) on the disposition of the ordinary share and your tax basis (in U.S. dollars) in the ordinary share. 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 ordinary share 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. As discussed above in “—Passive Foreign Investment Company,” however, we may be a PFIC for our current taxable year and future taxable years. If we are a PFIC, any such gain will be subject to the PFIC rules, as discussed above, rather than being taxed as capital gain. See “—Passive Foreign Investment Company” above.

Information Reporting and Backup Withholding

Dividend payments with respect to our ordinary shares and proceeds from the sale, exchange or other disposition of ordinary shares 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 our ordinary shares. U.S. Holders should consult their tax advisors regarding the possible implications of these tax return disclosure obligations.

UNDERWRITING

Under the terms of an underwriting agreement, which will be filed as an exhibit to the registration statement, each of the underwriters named below has severally agreed to subscribe for the respective number of ordinary shares shown opposite its name below:

<u>Underwriters</u>	<u>Number of Ordinary Shares</u>
Total	

The underwriting agreement provides that the underwriters' obligation to subscribe for ordinary shares depends on the satisfaction of the conditions contained in the underwriting agreement including:

- the obligation to subscribe for all of the ordinary shares offered hereby (other than those ordinary shares covered by their option to subscribe for additional ordinary shares as described below), if any of the ordinary shares are subscribed;
- the representations and warranties made by us to the underwriters are true;
- there is no material change in our business or the financial markets; and
- we deliver customary closing documents to the underwriters.

Commissions and Expenses

The following table summarizes the underwriting commissions we will pay to the underwriters. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to subscribe for additional ordinary shares. The underwriting fee is the difference between the initial price to the public and the amount the underwriters pay to us for the ordinary shares.

	<u>No Exercise</u>	<u>Full Exercise</u>
Per Share	\$	\$
Total	\$	\$

The underwriters have advised us that they propose to offer the ordinary shares directly to the public at the public offering price on the cover of this prospectus and to selected dealers, which may include the underwriters, at such offering price less a selling concession not in excess of \$ per share. After the offering, the underwriters may change the offering price and other selling terms.

The expenses of the offering that are payable by us are estimated to be approximately \$ (excluding underwriting commissions).

Option to Subscribe for Additional Ordinary Shares

We have granted the underwriters an option exercisable for 30 days after the date of this prospectus to subscribe, from time to time, in whole or in part, for up to an aggregate of ordinary shares at the public offering price less underwriting commissions. This option may be exercised to the extent the underwriters sell more than ordinary shares in connection with this offering. To the extent that this option is exercised, each underwriter will be obligated, subject to certain conditions, to subscribe for its pro rata portion of these additional ordinary shares based on the underwriter's percentage underwriting commitment in this offering as indicated in the table at the beginning of this Underwriting section.

Lock-Up Agreements

We, all of our board members and members of our senior management and the holders of substantially all of our outstanding ordinary shares have agreed that, for a period of days after the date of this prospectus, subject to certain limited exceptions as described below, we and they will not directly or indirectly, without the prior written consent of the underwriters, (1) offer for sale, sell, pledge, or otherwise dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any ordinary shares (including, without limitation, ordinary shares that may be deemed to be beneficially owned by us or them in accordance with the rules and regulations of the SEC and ordinary shares that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for ordinary shares, (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of ordinary shares, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of ordinary shares or other securities, in cash or otherwise, (3) make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any ordinary shares or securities convertible, exercisable or exchangeable for ordinary shares or any of our other securities, or (4) publicly disclose the intention to do any of the foregoing.

The underwriters in their sole discretion, may release the ordinary shares and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release ordinary shares and other securities from lock-up agreements, the underwriters will consider, among other factors, the holder's reasons for requesting the release, the number of ordinary shares and other securities for which the release is being requested and market conditions at the time. At least three business days before the effectiveness of any release or waiver of any of the restrictions described above with respect to an officer or director of our company, the underwriters will notify us of the impending release or waiver and we have agreed to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver, except where the release or waiver is effected solely to permit a transfer of ordinary shares that is not for consideration and where the transferee has agreed in writing to be bound by the same terms as the lock-up agreements described above to the extent and for the duration that such terms remain in effect at the time of transfer.

Offering Price Determination

Prior to this offering, there has been no public market for our ordinary shares. The initial public offering price was negotiated between the underwriters and us. In determining the initial public offering price of our ordinary shares, the underwriters considered:

- the history and prospects for the industry in which we compete;
- our financial information;
- the ability of our senior management and our business potential and earning prospects;
- the prevailing securities markets at the time of this offering; and
- the recent market prices of, and the demand for, publicly traded shares of generally comparable companies.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

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Stabilization, Short Positions and Penalty Bids

The underwriters may engage in stabilizing transactions, short sales and purchases to cover positions created by short sales, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the ordinary shares, in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- A short position involves a sale by the underwriters of ordinary shares in excess of the number of ordinary shares the underwriters are obligated to subscribe in this offering, which creates the syndicate short position. This short position may be either a covered short position or a naked short position. In a covered short position, the number of ordinary shares involved in the sales made by the underwriters in excess of the number of ordinary shares they are obligated to purchase is not greater than the number of ordinary shares that they may subscribe by exercising their option to subscribe for additional ordinary shares. In a naked short position, the number of ordinary shares involved is greater than the number of shares in their option to subscribe for additional ordinary shares. The underwriters may close out any short position by either exercising their option to subscribe for additional ordinary shares and/or purchasing ordinary shares in the open market. In determining the source of ordinary shares to close out the short position, the underwriters will consider, among other things, the price of ordinary shares available for purchase in the open market as compared to the price at which they may subscribe for ordinary shares through their option to subscribe for additional ordinary shares. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the ordinary shares in the open market after pricing that could adversely affect investors who purchase in this offering.
- Syndicate covering transactions involve purchases of the ordinary shares in the open market after the distribution has been completed in order to cover syndicate short positions.
- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the ordinary shares originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our ordinary shares or preventing or retarding a decline in the market price of the ordinary shares. As a result, the price of the ordinary shares may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The NASDAQ Global Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the ordinary shares. In addition, neither we nor any of the underwriters make any representation that the underwriters will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

Listing on The NASDAQ Global Market

We intend to apply to list our ordinary shares on The NASDAQ Global Market under the symbol “ .”

Stamp Taxes

If you subscribe for ordinary shares offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of subscriber, in addition to the offering price listed on the cover page of this prospectus.

Other Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment

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management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for the issuer and its affiliates, for which they received or may in the future receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer or its affiliates. If the underwriters or their affiliates have a lending relationship with us, certain of those underwriters or their affiliates routinely hedge, and certain other of those underwriters or their affiliates may hedge, their credit exposure to us consistent with their customary risk management policies. Typically, the underwriters and their affiliates would hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the ordinary shares offered hereby. Any such credit default swaps or short positions could adversely affect future trading prices of the ordinary shares offered hereby. The underwriters and certain of their affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

This prospectus does not constitute an offer to sell to, or a solicitation of an offer to buy from, anyone in any country or jurisdiction (i) in which such an offer or solicitation is not authorized, (ii) in which any person making such offer or solicitation is not qualified to do so or (iii) in which any such offer or solicitation would otherwise be unlawful. No action has been taken that would, or is intended to, permit a public offer of the ordinary shares or possession or distribution of this prospectus or any other offering or publicity material relating to the ordinary shares in any country or jurisdiction (other than the United States) where any such action for that purpose is required. Accordingly, each underwriter has undertaken that it will not, directly or indirectly, offer or sell any ordinary shares or have in its possession, distribute or publish any prospectus, form of application, advertisement or other document or information in any country or jurisdiction except under circumstances that will, to the best of its knowledge and belief, result in compliance with any applicable laws and regulations and all offers and sales of ordinary shares by it will be made on the same terms.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relevant Member State”) an offer to the public of any ordinary shares which are the subject of the offering contemplated herein may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any ordinary shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to legal entities which are qualified investors as defined under the Prospectus Directive;
- by the underwriters to fewer than 100, or, if the Relevant Member State has implemented the relevant provisions of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriters for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of ordinary shares shall result in a requirement for us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

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Each person in a Relevant Member State who receives any communication in respect of, or who acquires any ordinary shares under, the offers contemplated here in this prospectus will be deemed to have represented, warranted and agreed to and with each underwriter and us that:

- it is a qualified investor as defined under the Prospectus Directive; and
- in the case of any ordinary shares acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (i) the ordinary shares acquired by it in the offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in the circumstances in which the prior consent of the underwriters has been given to the offer or resale or (ii) where ordinary shares have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of such ordinary shares to it is not treated under the Prospectus Directive as having been made to such persons.

For the purposes of this representation and the provision above, the expression an “offer of ordinary shares to the public” in relation to any ordinary shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any ordinary shares to be offered so as to enable an investor to decide to subscribe for the ordinary shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

United Kingdom

This prospectus has only been communicated or caused to have been communicated and will only be communicated or caused to be communicated as an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act of 2000 (the “FSMA”)) as received in connection with the issue or sale of the ordinary shares in circumstances in which Section 21(1) of the FSMA does not apply to us. All applicable provisions of the FSMA will be complied with in respect to anything done in relation to the ordinary shares in, from or otherwise involving the United Kingdom.

EXPENSES OF THIS OFFERING

The following table sets forth the costs and expenses, other than the underwriting commissions, payable by us in connection with the sale of ordinary shares being registered. All amounts are estimates except for the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and The NASDAQ Global Market listing fee.

<u>Item</u>	<u>Amount to be paid</u>
SEC registration fee	\$ *
FINRA filing fee	*
The NASDAQ Global Market Listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue Sky, qualification fees and expenses	*
Transfer Agent fees and expenses	*
Miscellaneous expenses	*
Total	\$ *

* To be completed by amendment.

LEGAL MATTERS

The validity of the issuance of our ordinary shares offered in this prospectus and certain other matters of Danish law will be passed upon for us by Mazanti-Andersen Korsø Jensen, Copenhagen, Denmark. Certain matters of U.S. law will be passed upon for us by Latham & Watkins LLP, Menlo Park, California. are acting as counsel for the underwriters in connection with this offering.

EXPERTS

The consolidated financial statements as of December 31, 2013, December 31, 2012 and January 1, 2012, and for each of the two years in the period ended December 31, 2013 included in this Registration Statement, have been audited by Deloitte Statsautoriseret Revisionspartnerselskab, an independent registered public accounting firm, as stated in their report appearing herein and elsewhere in the Registration Statement (which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph referring to the restatement of the previously issued consolidated financial statements for the year ended December 31, 2013 and substantial doubts over going concern, as described in Note 1). Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing. The offices of Deloitte Statsautoriseret Revisionspartnerselskab are located at Weidekampsgade 6, 2300 Copenhagen, Denmark.

ENFORCEMENT OF CIVIL LIABILITIES

We are organized under the laws of Denmark, with domicile in the municipality of Copenhagen, Denmark.

Some of the members of the board of directors and the executive board named herein are residents of Denmark or other jurisdictions outside the United States. All or a substantial portion of ours and such persons' assets are located in Denmark or other jurisdictions outside the United States. As a result, it may not be possible for investors to effect service of process upon such persons or us with respect to litigation that may arise under U.S. federal securities law or to enforce against them or our company judgments obtained in U.S. courts, whether or not such judgments were made pursuant to civil liability provisions of the federal or state securities laws of the United States or any other laws of the United States.

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We have been advised by our Danish legal advisors, Mazanti-Andersen Korsø Jensen, that there is not currently a treaty between the United States and Denmark providing for reciprocal recognition and enforceability of judgments rendered in connection with civil and commercial disputes and, accordingly, that a final judgment rendered by a U.S. court based on civil liability would not be enforceable in Denmark. Considerable uncertainty exists whether Danish courts would allow actions to be predicated on the securities laws of the United States or other jurisdictions outside Denmark. Awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Denmark.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act with respect to the ordinary shares offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to Ascendis Pharma and the ordinary shares offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street N.E., Room 1580, Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address is www.sec.gov.

After this offering, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, applicable to foreign private issuers. Because we are a foreign private issuer, the SEC's rules do not require us to deliver proxy statements or to file quarterly reports on Form 10-Q, among other things. However, we plan to produce quarterly financial reports and furnish them to the SEC after the end of each of the first three quarters of our fiscal year and to file our annual report on Form 20-F within four months after the end of our fiscal year. In addition, our "insiders" are not subject to the SEC's rules that prohibit short-swing trading. Our annual consolidated financial statements will be prepared in accordance with IFRS as issued by the IASB and certified by an independent public accounting firm.

ASCENDIS PHARMA A/S

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Report of independent registered public accounting firm

**To the Board of Directors and Shareholders of Ascendis Pharma A/S.
Hellerup, Denmark**

We have audited the accompanying consolidated statements of financial position of Ascendis Pharma A/S and subsidiaries (the "Company") as of December 31, 2013, December 31, 2012 and January 1, 2012, and the consolidated statements of profit or loss and other comprehensive income, the consolidated statements of changes in equity, and the consolidated cash flow statements for each of the two years in the period ended December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Ascendis Pharma A/S and subsidiaries as of December 31, 2013, December 31, 2012 and January 1, 2012, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2013, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

The consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, on June 30, 2014, the Company received a notice from one of its collaboration partners informing the Company of such partner's intent to terminate its collaboration agreement with the Company, which has reduced the Company's expected future cash flows and gives rise to a substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Further as discussed in Note 1 to the consolidated financial statements, the accompanying consolidated financial statements for the year ended December 31, 2013 have been restated to correct a misstatement in the calculation of tax on profit for the year recognised in the consolidated statements of profit or loss and other comprehensive income.

Deloitte Statsautoriseret Revisionspartnerselskab

Copenhagen, August 1, 2014

/s/ Jens Sejer Pedersen
State Authorised
Public Accountant

/s/ Flemming Larsen
State Authorised
Public Accountant

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

	Notes	Consolidated	
		2013 (Restated)	2012
		(EUR'000)	
Revenue	3	20,408	15,583
Research and development costs		(12,713)	(11,380)
General and administrative expenses		(2,416)	(2,690)
Operating profit		5,279	1,513
Finance income	6	158	4
Finance expenses	6	(732)	(232)
Profit before tax		4,705	1,285
Tax on profit for the year	7	(626)	(35)
Net profit for the year		4,079	1,250
Other comprehensive income			
<i>Items that may be reclassified subsequently to profit or loss:</i>			
Exchange differences on translating foreign operations		(6)	(51)
Other comprehensive loss for the year, net of tax		(6)	(51)
Total comprehensive income for the year, net of tax		4,073	1,199
Profit for the year attributable to owners of the Company		4,079	1,250
Total comprehensive income for the year attributable to owners of the Company		4,073	1,199
		<u>EUR</u>	<u>EUR</u>
Basic and diluted earnings per share, preference C shares		1.94	0.57
Basic and diluted earnings per share, preference B shares		—	—
Basic and diluted earnings per share, ordinary shares		—	—

Dividends shall be distributed in accordance with the Shareholders' Agreement, according to which holders of preference C shares will be entitled to receive an amount per preference C share corresponding to the subscription price paid per preference C share. Accordingly, no part of the profit for the year will be attributable to holders of ordinary shares. As the outstanding equity instruments will convert into ordinary shares, it will not be entitled to dividends for the years presented and accordingly, basic and diluted earnings per share are identical.

Please refer to Note 1 for an explanation of the restatement.

Consolidated Statements of Financial Position

As of

	Notes	Consolidated		
		December 31, 2013 (Restated)	December 31, 2012	January 1, 2012
		(EUR'000)		
Assets				
Non-current assets				
Intangible assets	8	3,495	3,495	3,495
Property, plant and equipment	9	1,974	1,184	1,318
Deposits		32	30	31
		<u>5,501</u>	<u>4,709</u>	<u>4,844</u>
Current assets				
Trade receivables		1,705	5,718	1,242
Other receivables		—	353	778
Prepayments		64	90	271
Cash and cash equivalents		19,430	14,535	15,683
		<u>21,199</u>	<u>20,696</u>	<u>17,974</u>
Total assets		<u>26,700</u>	<u>25,405</u>	<u>22,818</u>
Equity and liabilities				
Equity				
Share capital	11	362	362	362
Other reserves	12	2,719	2,054	1,980
Retained earnings/(accumulated deficit)		3,220	(860)	(2,109)
Total equity		<u>6,301</u>	<u>1,556</u>	<u>233</u>
Non-current liabilities				
Finance lease liabilities		—	—	213
		<u>—</u>	<u>—</u>	<u>213</u>
Current liabilities				
Finance lease liabilities		—	212	187
Trade payables and other payables		2,520	2,532	2,518
Deferred income	13	17,470	21,084	19,667
Income taxes payable	7	409	21	—
		<u>20,399</u>	<u>23,849</u>	<u>22,372</u>
Total liabilities		<u>20,399</u>	<u>23,849</u>	<u>22,585</u>
Total equity and liabilities		<u>26,700</u>	<u>25,405</u>	<u>22,818</u>

Please refer to Note 1 for an explanation of the restatement.

Consolidated Statements of Changes in Equity

	Share Capital	Foreign Currency Translation Reserve	Share-based Payment Reserve (EUR'000)	Retained Earnings	Total
Equity at January 1, 2012 (as previously reported under Danish GAAP)	362	—	—	16,549	16,911
Effects of conversion to EUR	—	—	—	(11)	(11)
IFRS adjustments (Note 18)	—	—	1,980	(18,647)	(16,667)
Equity at January 1, 2012 (according to IFRS)	362	—	1,980	(2,109)	233
Profit for the year	—	—	—	1,250	1,250
Other comprehensive loss, net of tax	—	(51)	—	—	(51)
Total comprehensive (loss)/income	—	(51)	—	1,250	1,199
Share-based payment (Note 5)	—	—	124	—	124
Equity at December 31, 2012	362	(51)	2,105	(859)	1,556
Profit for the year (restated)	—	—	—	4,079	4,079
Other comprehensive loss, net of tax	—	(6)	—	—	(6)
Total comprehensive loss/income (restated)	—	(6)	—	4,079	4,073
Share-based payment (Note 5)	—	—	671	—	671
Equity at December 31, 2013 (restated)	362	(57)	2,776	3,220	6,301

Please refer to Note 1 for an explanation of the restatement.

Consolidated Cash Flow Statements for the year Ended December 31

	Consolidated	
	2013	2012
	(Restated)	
	(EUR'000)	
Operating activities		
Net profit for the year	4,079	1,250
Reversal of finance income	(158)	(4)
Reversal of finance expenses	732	232
Reversal of tax charge	626	35
Adjustments for:		
Share-based payment	671	125
Depreciation and amortization	405	425
Changes in working capital:		
Deposits	(2)	1
Trade receivables	4,013	(4,476)
Other receivables	353	425
Prepayments	26	182
Trade payables and other payables	(12)	13
Deferred income	(3,614)	1,417
Income taxes payable	(239)	(14)
Cash flows generated from/(used in) operations	6,880	(389)
Finance income received	115	159
Finance expenses paid	(685)	(422)
Cash flows from/(used in) operating activities	6,310	(652)
Investing activities		
Acquisition of property, plant and equipment	(1,195)	(291)
Cash flows used in investing activities	(1,195)	(291)
Financing activities		
Installments on long-term financial liabilities	(220)	(205)
Cash flows used in financing activities	(220)	(205)
Increase / (decrease) in cash and cash equivalents	4,895	(1,148)
Cash and cash equivalents at January 1	14,535	15,683
Cash and cash equivalents at December 31	19,430	14,535

Please refer to Note 1 for an explanation of the restatement.

Notes to the Consolidated Financial Statements

Note 1—Summary of Significant Accounting Policies

Ascendis Pharma A/S is a company incorporated in 2006 and headquartered in Hellerup, Denmark. Ascendis Pharma A/S, together with its subsidiaries, is a biotechnology company that applies its TransCon technology to develop a pipeline of long-acting prodrug therapies with best-in-class profiles that address large markets with significant unmet medical needs. Unless the context otherwise requires, references to the “company,” “Ascendis,” “we,” “us” and “our” refer to Ascendis Pharma A/S and its subsidiaries.

The address of its registered office is Tuborg Boulevard 12, DK-2900 Hellerup.

Going Concern

We have been engaged in research and development activities since we commenced operations in 2007, and have funded our operations through the issuance of equity, convertible debt, and by entering into collaboration agreements that provide up-front payments, milestone payments and service fees. Our consolidated financial statements have been prepared on the basis that we are a going concern and do not include any adjustments that may be necessary should we be unable to continue as a going concern.

In June 2014, we received a notice from United Therapeutics informing us of its intent to terminate the collaboration agreement for convenience, and we are in the process of negotiating termination of the agreement and the transition of the program back to us. The termination of the collaboration agreement has reduced the milestone payments and service fees we expected to receive in 2014, as well as future milestone payments. Accordingly, we believe that our cash position of approximately €19.4 million as of December 31, 2013, and our projected cash inflow from operating activities during 2014, will not be sufficient to meet our obligations, support our operations and fully execute our strategic plan through December 31, 2014.

To execute our plans through 2014, we must obtain additional cash through the issuance of equity or debt, or enter into new collaboration agreements that provide up-front payments, milestone payments or service fees for use in funding our operations. Substantial revenue streams will likely not be available until and unless we are able to enter into new strategic collaborations with substantial up-front payments, advance development of products covered under our current collaborations with Sanofi and Genentech to a stage that results in milestone payments to us, or when and if any of our product candidates are approved by the FDA, the EMA or comparable regulatory authorities in other countries and successfully commercialized, either by us or one of our collaboration partners. Therefore, our continuation as a going concern is dependent upon our ability to obtain additional funding. There is no assurance that additional funding will be available when needed on acceptable terms, or at all, or that it will be available in amounts that will allow us to continue as a going concern. Accordingly, there exists substantial doubt regarding our ability to continue as a going concern.

Changes in Accounting Policies

Prior to 2013, we prepared our consolidated financial statements in accordance with Generally Accepted Accounting Principles in Denmark, or Danish GAAP, and the presentation currency of those consolidated financial statements was the Danish Krone, or DKK. Effective January 1, 2013, we changed our presentation currency to the Euro, or EUR, and began presenting our consolidated financial statements in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, and IFRS as adopted by the European Union, or EU.

The consolidated financial statements for 2013 are our first set of consolidated financial statements that comply with IFRS. The application of IFRS effective for the financial year beginning January 1, 2013 require an IFRS

transition date as of January 1, 2012. Pursuant to IFRS, the comparative figures have been restated. The accounting policies applied when preparing the consolidated financial statements are described in detail below. Significant accounting estimates used when exercising the accounting policies are described in Note 2. The effects of the transition to financial reporting under IFRS are described in Note 18.

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.

Restatement of Previously Issued Consolidated Financial Statements

We filed our statutory annual report for the year ended December 31, 2013 with the Danish authorities on June 2, 2014, including consolidated financial statements for the company prepared under IFRS as adopted by the EU, authorized for issuance on June 2, 2014. Those consolidated financial statements did not appropriately reflect the company's tax charge for the fiscal year ended December 31, 2013. The tax calculation incorrectly assumed that certain tax losses carried forward within the group of jointly taxed Danish companies could be fully offset against the taxable income earned in one of the subsidiaries of Ascendis Pharma A/S. However, Danish tax law imposes limitations to the offsetting of tax losses against tax profits within each fiscal year, and accordingly, the taxable income could not be fully offset by the tax losses carried forward within the company. As a result, an additional tax provision of €0.4 million thousand has been recognized in these restated consolidated financial statements. The restatement has impacted the consolidated financial statements for the year ended December 31, 2013 as follows:

	As originally reported	Consolidated	
		Restatement	Amount as adjusted
		(EUR'000)	
Tax on profit for the year	(217)	(409)	(626)
Net profit for the year	4,488	(409)	4,079
Total comprehensive income for the year, net of tax	4,482	(409)	4,073
Profit for the year attributable to owners of the Company	4,488	(409)	4,079
Total comprehensive income for the year attributable to owners of the Company	4,482	(409)	4,073
Retained earnings	3,629	(409)	3,220
Total Equity	6,710	(409)	6,301
Income taxes payable	—	409	409
Current liabilities	19,990	409	20,399
Total liabilities	19,990	409	20,399

Recognition and Measurement

Assets are recognized in the consolidated statement of financial position when it is probable, as a result of a prior event, that future economic benefits will flow to us and the value of the asset can be measured reliably.

Liabilities are recognized in the consolidated statement of financial position when we have a legal or constructive obligation as a result of a prior event, and it is probable that future economic benefits will flow from us and the value of the liability can be measured reliably.

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.

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Notes to the Consolidated Financial Statements

Anticipated risks and losses that arise before the time of presentation of the annual report and that confirm or invalidate affairs and conditions existing at the consolidated statement of financial position date are considered at the time of recognition and measurement.

Income is recognized in the income statement when earned, whereas costs are recognized by the amounts attributable to the financial year.

Basis of Consolidation

The consolidated financial statements include our parent company, Ascendis Pharma A/S, and all entities over which the parent company has control. We control an entity when we are exposed to, or have rights to, variable returns from our involvement with the entity and have the ability to control those returns through our power over the entity. Accordingly, the consolidated financial statements include Ascendis Pharma A/S and the following group of entities:

<u>Company</u>	<u>Domicile</u>	<u>Ownership</u>
Ascendis Pharma GmbH	Germany	100%
Ascendis Pharma, Inc.	US	100%
Ascendis Pharma, Ophthalmology Division A/S	Denmark	100%
Ascendis Pharma, Growth Disorders Division A/S	Denmark	100%
Ascendis Pharma, Osteoarthritis Division A/S	Denmark	100%
Ascendis Pharma, Circulatory Diseases Division A/S	Denmark	100%

Consolidation Principles

Our subsidiaries are fully consolidated from the date upon which control is transferred to us. They are deconsolidated from the date control ceases.

When necessary, adjustments are made to the financial statements of our subsidiaries to conform their accounting policies to our accounting policies. All intra-company assets and liabilities, equity, income, expenses and cash flows relating to transactions between our group enterprises are eliminated in full upon consolidation.

Foreign Currency

On initial recognition, transactions in currencies other than an individual company's functional currency are translated applying the exchange rate in effect at the date of the transaction. Receivables, payables and other monetary items denominated in foreign currencies that have not been settled at the balance sheet date are translated using the exchange rate in effect at the balance sheet date.

Exchange differences that arise between the rate at the transaction date and the rate in effect at the payment date, or the rate at the balance sheet date, are recognized in profit or loss as financial income or financial expenses. Property, plant and equipment, intangible assets, inventories and other non-monetary assets purchased in foreign currencies and measured on the basis of historical cost are translated at the transaction date exchange rate.

When subsidiaries that present their financial statements in a functional currency other than EUR are recognized in the consolidated financial statements, the income statements are translated at average exchange rates on a quarterly basis, unless such rates vary significantly from the actual exchange rates at the transaction date. In the latter case, the actual exchange rates are applied. Balance sheet items are translated using the exchange rates at the balance sheet date.

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Notes to the Consolidated Financial Statements

Exchange differences arising out of the translation of foreign entities' balance sheet items at the beginning of the year using the balance sheet date exchange rates as well as out of the translation of income statements from average rates to the exchange rates at the balance sheet date are recognized in other comprehensive income. Similarly, exchange differences arising out of changes that have been made directly in a foreign subsidiary's equity are recognized in other comprehensive income.

Business Combinations

Newly acquired or newly established subsidiaries are recognized in the consolidated financial statements from the time of acquiring or establishing such enterprises. Time of acquisition is the date on which control of the enterprise is actually acquired.

When acquiring new enterprises over which we obtain control, the acquisition method is applied. Under this method, we identify assets, liabilities and contingent liabilities of these enterprises and measure them at fair value at the acquisition date. Restructuring costs are only recognized in the pre-acquisition balance sheet if they constitute a liability of the acquired enterprise. Allowance is made for the tax effect of the adjustments made.

The acquisition consideration for an enterprise consists of the fair value of the consideration paid for the acquired enterprise. If the final determination of the consideration is conditional upon one or several future events, they are recognized at fair value thereof at the time of acquisition. Costs that are attributable to the acquisition of the enterprise are recognized in profit or loss when incurred.

The excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the identifiable net assets acquired are all recorded as goodwill.

Statement of Comprehensive Income

Revenue

Our revenue currently comprises up-front payments and service fees from research, development and commercialization agreements. Our collaboration agreements comprise elements of up-front license fees, milestone payments based on development and sales and royalties based on product sales. In addition, our collaboration agreements contemplate our involvement in the ongoing research and development of our partnered product candidates, for which we are separately remunerated for the services we render.

As a general principle, revenue is recognized when it is probable that future economic benefits will flow to us and these benefits can be measured reliably. Further, revenue recognition requires that all significant risks and rewards of ownership of the goods or services included in the transaction have been transferred to the buyer, and that we retain neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods or services sold.

Collaboration agreements which contain multiple activities are only separated into individual units of accounting if they constitute a separate earnings process. If multiple activities or rights are not separable, they are combined into a single unit of accounting, and recognized over the period of continued involvement; i.e. the period where we are actively involved in development and deliver significant services to the collaboration partner. If multiple activities or rights are separable, each separate component is accounted for after considering the specific nature of the element and the underlying activities to which earnings process relates. For the two years ended December 31, 2013 and 2012, the collaboration agreements entered into by the company did not meet the criteria for separation, and all arrangements were accounted for as a single unit of account. Accordingly, the up-front license payments have been recognised as revenue over the period of continued involvement. In addition, the

milestone criteria and sales-based royalty thresholds have not yet been met and such thresholds are not yet considered probable, accordingly no milestone and royalty payments have been received or are expected to be received.

If we are entitled to reimbursement from our collaborators for specified research and development expenses and/or entitled to payments for specified research and development services that we provide, we determine whether the research and development funding would result in collaborative revenues or an offset to research and development expenses. Where the payment is for specific research and development services that are to be accounted for as collaborative revenue, such revenue is recognized when such services are provided. Where such payments are not to be considered to be collaborative revenue but are considered to be reimbursements for external expenses incurred, the reimbursements are offset against research and development costs.

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

Revenue is measured at fair value of the consideration received or receivable. Revenue is stated net of value added tax, duties, etc. collected on behalf of a third party and discounts.

Research and Development Costs

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

Government grants received to cover expenses incurred are recognized in research and development costs.

Research costs are recognized in the income statement in the period to which they relate. Development costs are recognized in the income statement when incurred if the criteria for capitalization have not been met.

A development project involves a single product candidate undergoing a series of studies to illustrate its safety profile and effect on human beings prior to obtaining the necessary approval from the appropriate authorities. Due to the risk related to the development of pharmaceutical products, we cannot estimate the future economic benefits associated with individual development projects with sufficient certainty until the development project has been finalized and the necessary market approval of the final product has been obtained. As a consequence, all development costs are recognized in the income statement in the period to which they relate.

General and Administrative Expenses

General and administrative expenses comprise salaries, share-based payment, and other staff costs including pensions, office supplies, cost of premises, and depreciation and amortization related to administrative activities.

General and administrative expenses are recognized in the income statement in the period to which they relate.

Government Grants

Government grants are recognized when there is reasonable assurance that the conditions underlying the grants have been met and that the grant will be received.

Government grants to cover expenses incurred are recognized in profit or loss proportionally over the periods during which the related expenses are recognized in profit or loss. The grants are off-set against the expenses incurred and thus reduce our research and development costs.

Share-based Incentive Programs

Share-based incentive programs under which board members, employees and external consultants have the option to purchase shares in Ascendis Pharma A/S (equity-settled share-based payment arrangements) are measured at the equity instrument's fair value at the grant date.

The cost of equity-settled transactions is determined by the fair value at the date of grant using the Black-Scholes valuation model. The cost is recognized together with a corresponding increase in equity over the period in which the performance and/or service conditions are fulfilled, the vesting period. The fair value determine at the grant date of the equity-settled share-based payment is expensed on a straight line basis over the vesting period for each tranche, based on our best estimate of the number of equity instruments that will ultimately vest. No expense is recognized for grants that do not ultimately vest.

Where an equity-settled grant is cancelled, it is treated as if it vested on the date of the cancellation, and any expense not yet recognized for the grant is recognized immediately. This includes any grant where non-vesting conditions within the control of either the entity or the employee are not met. However, if a new grant is substituted for the cancelled grant, and designated as a replacement grant on the date that it is granted, the cancelled and new grants are treated as if they were a modification of the original grant, as described in the previous paragraph. All cancellations of equity-settled transaction grants are treated equally.

Any social security contributions payable in connection with the grant of the warrants are considered an integral part of the grant itself and the charge is treated as a cash-settled transaction, by which a liability is accrued over the vesting period based on the social security contributions arising from the potential gain on exercise of the warrants. For the purpose of estimating the accrued social security contribution, the potential gain on exercise of warrants is estimated as the difference between the exercise price of the warrant and the market price of our ordinary shares, or the intrinsic value of the warrants.

The assumptions used for estimating the fair value of share-based payment transactions are disclosed in Note 5.

Finance Income and Expenses

Finance income and expenses comprise interest income and expenses, the interest portion related to finance lease contracts and realized and unrealized exchange rate gains and losses on transactions denominated in foreign currencies.

Interest income and interest expenses are stated on an accrual basis using the principal and the effective interest rate. The effective interest rate is the discount rate that is used to discount expected future payments related to the financial asset or the financial liability in order for the present value of such asset or liability to match their carrying amount.

Income Taxes

Tax for the year, which consists of current tax for the year and changes in deferred tax, is recognized in profit or loss by the portion attributable to the profit or loss for the year and recognized directly in equity or other comprehensive income by the portion attributable to entries directly in equity and in other comprehensive income.

The current tax payable or receivable is recognized in the balance sheet, stated as tax computed on this year's taxable income, adjusted for prepaid tax.

When computing the current tax for the year, the tax rates and tax rules enacted or substantially enacted at the balance sheet date are used.

Deferred tax is recognized according to the balance sheet liability method of all temporary differences between carrying amounts and tax-based values of assets and liabilities, apart from deferred tax on all temporary differences occurring on initial recognition of goodwill or on initial recognition of a transaction which is not a business combination, and for which the temporary difference found at the time of initial recognition neither affects net profit or loss nor taxable income.

Deferred tax liabilities are recognized on all temporary differences related to investments in our subsidiaries, unless we are able to control when the deferred tax is realized, and it is probable that the deferred tax will not become due and payable as current tax in the foreseeable future.

Deferred tax is calculated based on the planned use of each asset and the settlement of each liability, respectively.

Deferred tax is measured using the tax rates and tax rules in the relevant countries that, based on acts in force or acts in reality in force at the balance sheet date, are expected to apply when the deferred tax is expected to crystallize as current tax. Changes in deferred tax resulting from changed tax rates or tax rules are recognized in profit or loss unless the deferred tax is attributable to transactions previously recognized directly in equity or other comprehensive income. In the latter case, such changes are also recognized in equity or other comprehensive income.

Deferred tax assets, including the tax base of tax loss carry forwards, are recognized in the balance sheet at their estimated realizable value, either as a set-off against deferred tax liabilities or as net tax assets for offset against future positive taxable income. At every balance sheet date, it is assessed whether sufficient taxable income is likely to arise in the future for the deferred tax asset to be used.

Statement of Financial Position

Intangible Assets

Goodwill

Goodwill is initially measured at cost, being the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests over the net identifiable assets acquired and liabilities assumed. After initial recognition, goodwill is measured at cost less any accumulated impairment losses. Goodwill is not amortized but is subject to impairment testing at least on a yearly basis. For the purpose of impairment testing, goodwill acquired in a business combination is allocated to each of the cash-generating units, or group of cash-generating units, that are expected to benefit from the synergies of the combination. Each cash-generating unit or group of cash generating units to which goodwill is allocated represent the lowest level within the Company at which the goodwill is monitored for internal management purposes. Goodwill is monitored at the consolidated level.

Property, Plant and Equipment

Property, plant and equipment is measured at cost less accumulated depreciation and impairment losses. Cost comprises the acquisition price, costs directly attributable to the acquisition and preparation costs of the asset until the time when it is ready to be put into operation. For assets held under finance leases, cost is the lower of the asset's fair value and net present value of future lease payments.

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Notes to the Consolidated Financial Statements

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 income statement during the financial periods in which they are incurred.

If the acquisition or use of the asset involves an obligation to incur costs of decommissioning or restoration of the asset, the estimated related costs are recognized as a provision and as part of the relevant asset's cost, respectively.

The basis of depreciation is cost less estimated residual value. The residual value is the estimated amount that would be earned if selling the asset today net of selling costs, assuming that the asset is of an age and a condition that is expected after the end of its useful life. The cost of a combined asset is divided into smaller components, with such components depreciated individually if their useful lives vary.

Depreciation is calculated on a straight-line basis from the following assessment of an asset's expected useful life:

Process plant and machinery	5 - 10 years
Other fixtures and fittings, tools and equipment	3 - 5 years
Leasehold improvements	3 - 5 years

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

Property, plant and equipment are written down to the lower of recoverable amount and carrying amount, as described in the "Impairment" section below.

Depreciation, impairment losses and gains and losses on disposal of property, plant and equipment are recognized in the statements of profit/(loss) as research and development costs or as general and administrative expenses, as appropriate.

Impairment

Property, plant and equipment and finite-lived intangible assets are reviewed for impairment whenever events or circumstances indicate that the carrying amount may not be recoverable. The recoverable amount of goodwill is estimated annually irrespective of any recorded indications of impairment.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purpose of assessing impairment, assets are grouped at the lowest levels for which there are largely independent cash inflows, or cash-generating units, which for goodwill represent the lowest level within the entity at which the goodwill is monitored for internal management purposes. Prior impairments of non-financial assets, other than goodwill, are reviewed for possible reversal at each reporting date.

Receivables

Receivables comprise trade receivables and other receivables. Receivables are classified as loans and receivables constituting financial assets with fixed or determinable payments that are not listed on an active market and are not derivative financial instruments.

On initial recognition, receivables are measured at fair value and, subsequently, at amortized cost, usually equaling nominal value less a provision for bad debts. Provisions for bad debts are determined on the basis of an individual assessment of each receivable and recognized using an allowance account.

Prepayments

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

Cash and Cash Equivalents

Cash and cash equivalents comprise cash and demand deposits with financial institutions. Cash and cash equivalents are measured at fair value.

Shareholders' Equity

The share capital comprises the nominal amount of the parent company's ordinary shares, each at a nominal value of DKK 1, or approximately €0.13. All shares are fully paid.

Translation reserves include exchange rate adjustments of equity investments in our group enterprises.

Reserve for share-based payment represents the corresponding entries to the share-based payment recognized in the profit or loss, arising from our warrant programs.

Provisions

Provisions are recognized when we have an existing legal or constructive obligation as a result of events occurring prior to or on the balance sheet date, and it is probable that the utilization of economic resources will be required to settle the obligation. Provisions are measured as the best estimate of the expense necessary to settle the obligation at the balance sheet date. Provisions that are estimated to mature after more than one year after the balance sheet date are measured at their present values.

Leases

Leases of property, plant and equipment, where we have substantially all of the risks and rewards of ownership, are classified as finance leases. Other leases are classified as operating leases.

Assets held under finance leases are recognized in the balance sheet at the inception of the lease term at the lower of the fair value of the asset or the net present value of the future minimum lease payments. A liability equaling the asset is recognized in the balance sheet, allocated between non-current and current liabilities. Each lease payment is separated between an interest element, recognized as a financial expense, and a reduction of the lease liability.

Assets held under finance leases are depreciated over the shorter of the asset's useful life and the lease term.

Lease payments on operating leases are recognized on a straight-line basis in profit or loss over the term of the lease.

Total commitment under operating leases is disclosed in the notes to the consolidated financial statements.

Other Financial Liabilities

Other financial liabilities comprise trade payables, payables to public authorities and accrued expenses.

On initial recognition, other financial liabilities are measured at fair value less any transaction costs. Subsequently, these liabilities are measured at amortized cost applying the effective interest method to the effect

that the difference between proceeds and nominal amount is recognized in the income statement as a financial expense over the term of the loan.

Deferred Income

Deferred income comprises income received for recognition in subsequent financial years. Deferred income typically arises from up-front payments under our collaboration agreements related to license grants or up-front funding of development activities. If we are participating in continued development of product candidates, up-front payments are recognized as deferred income and recognized as revenue over the anticipated period in which we are involved in the development activities. Deferred income is measured at the fair value of the income received.

Cash Flow Statement

The cash flow statement shows cash flows from operating, investing and financing activities as well as cash and cash equivalents at the beginning and the end of the financial year.

Cash flows from operating activities are presented using the indirect method and calculated as the operating profit or loss adjusted for non-cash operating items, working capital changes as well as financial income, financial expenses and income taxes paid.

Cash flows from investing activities comprise payments in connection with acquisitions, development, improvement and sale, etc. of intangible assets, property, plant and equipment, and group enterprises.

Cash flows from financing activities comprise changes in the share capital of Ascendis Pharma A/S and related costs as well as the raising and repayment of loans and installments on interest-bearing debt. Cash flows from financing activities also include lease payments made on assets held under finance leases.

Cash flows in currencies other than the functional currency are recognized in the cash flow statement, using the average exchange rates for the individual quarters, unless they vary significantly from the actual exchange rate at the transaction dates. In the latter case, the actual exchange rates at the individual dates are used.

Cash and cash equivalents comprise cash at hand and deposits with financial institutions.

Segment Reporting

We are managed and operated as one operating and reportable segment. No separate operating segments or reportable segments have been identified in relation to product candidates or geographical markets. Accordingly, we do not disclose segment information on business segments or geographical markets.

Basic EPS

Basic Earnings per Share, or EPS, is calculated as the net income or loss from continuing operations for the period divided by the weighted average number of ordinary shares outstanding.

Diluted EPS

Diluted earnings per share is calculated as the net income or loss from continuing operations for the period divided by the weighted average number of ordinary shares outstanding adjusted for the dilutive effect of share equivalents.

If the income statement shows a net loss, no adjustment is made for the dilutive effect, as such effect would be anti-dilutive.

New International Financial Reporting Standards and Interpretations Not Yet Effective

The IASB has issued and the EU has adopted a number of new or amended standards and interpretations, which have not yet become effective. Therefore, these new standards and interpretations have not been incorporated in these consolidated financial statements. Our financial reporting is expected to be affected by such new or improved standards to the extent described below.

- IAS 32, “Offsetting Financial Assets and Financial Liabilities”—Amendments to IAS 32 clarify the meaning of “currently has a legally enforceable right to set-off”. The amendments also clarify the application of the IAS 32 offsetting criteria to settlement systems (such as central clearing house systems) which apply gross settlement mechanisms that are not simultaneous. These amendments are not expected to significantly impact our financial position or performance. These amendments become effective for annual periods beginning on or after January 1, 2014.
- IFRS 9, “Financial Instruments: Classification and Measurement” reflects the first phase of the IASB’s work on the replacement of IAS 39 and applies to classification and measurement of financial assets and financial liabilities as defined in IAS 39. The standard was initially effective for annual periods beginning on or after January 1, 2013, but Amendments to IFRS 9 Mandatory Effective Date of IFRS 9 and Transition Disclosures, issued in December 2011, moved the mandatory effective date to January 1, 2015. In subsequent phases, the IASB will address hedge accounting and impairment of financial assets. We are assessing the impact of this standard and will quantify the effect once the final standard is issued.
- IFRS 15 “Revenue from Contracts with Customers” establishes the principles that an entity shall apply to report useful information to users of financial statements about the nature, amount, timing, and uncertainty of revenue and cash flows arising from a contract with a customer. The objective of this project was to clarify the principles for recognizing revenue from contracts with customers. IFRS 15 requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is effective for an entity’s first annual IFRS financial statements for a period beginning on or after January 1, 2017. We are currently in the process of assessing the impact of this standard.

Note 2—Critical Accounting Judgments and Key Sources of Estimation Uncertainty

In the application of our accounting policies, we are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

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

Critical Judgments in Applying Accounting Policies

The following are the critical judgments, apart from those involving estimates, see below, made in the process of applying our accounting policies and that have the most significant effect on the amounts recognized in our consolidated financial statements.

Revenue Recognition

IAS 18, “Revenues” prescribes the criteria to be fulfilled for revenue being recognizable. Evaluating the criteria for revenue recognition with respect to our research and development and commercialization agreements requires judgment to ensure that all criteria have been fulfilled prior to recognizing any amount of revenue. We generate revenue from collaboration agreements which typically involve multiple elements, including licenses to our technology, transfer of patents, participation in joint development projects with our collaboration partners, and other services in various areas related to the development of new products. As part of evaluating the criteria for revenue recognition, we consider the separability of the individual deliverables in the collaboration agreements and potential allocation of the total consideration received to the individual elements of the agreement. Further, if any up-front elements are considered inseparable from a following development period, the appropriate allocation of an up-front payment over time needs to be determined.

We evaluate all of our revenue generating transactions to ensure recognition in accordance with IFRS.

In 2013, we signed an exclusive license agreement with Genentech within the field of ophthalmology. The agreement included an up-front payment and funding of research and development activities and entitles us to receive future development milestone payments and royalties on sales of licensed products. As the license granted to Genentech was interrelated to the agreed research and development activities, the deliverables were inseparable under IAS 18 and, accordingly, the up-front payment was recognized as deferred income to be recognized as revenue over the agreed research and development period. Accordingly, as of December 31, 2013, we recognized €12.9 million as deferred income with respect to this agreement. In total, we had €17.5 million in deferred income as of December 31, 2013 compared to €21.1 million as of December 31, 2012.

Share-Based Payment

IFRS 2, “Share-Based Payment” requires an entity to reflect in its profit or loss and financial position the effects of share-based payment transactions, including expenses associated with transactions in which share options are granted to employees. We have granted warrants to employees, consultants and board members under two different programs as described in Note 5, which need to be accounted for under IFRS 2.

We use the Black-Scholes option-pricing model to value the warrants granted and critical judgments need to be exercised in determining the appropriate input to the valuation model as well as to determine the appropriate way of recognizing the expenses under IFRS 2.

Warrants granted under our warrant programs vest on a monthly basis over periods of up to 48 months. Due to the graded vesting, the related expenses are recognized on an accelerated basis; i.e. each tranche of a warrant grant is treated separately for expense recognition purposes. Accordingly, each warrant grant is treated in up to 48 tranches, which are each recognized over the expected useful life of that particular tranche. In total €671 thousand was recognized as share-based payment in the consolidated financial statements for 2013 compared to €124 thousand for 2012.

See Note 5 for additional details on our warrant programs and recognition of expenses under IFRS 2.

Internally Generated Intangible Assets

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

the development project can be measured reliably; and (4) that we have the intent to produce and market the product or use it internally.

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

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

Joint Arrangements / Collaboration Agreements

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

Key Sources of Estimation Uncertainty

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

Impairment of Goodwill

Determining whether goodwill is impaired requires an estimation of the value in use of the cash-generating units to which goodwill has been allocated. The value in use calculation requires that we estimate future cash flows expected to arise from cash-generating units and a suitable discount rate in order to calculate present value. Where the actual future cash flows are less than expected, a material impairment loss may arise.

The carrying amount of goodwill at December 31, 2013 and December 31, 2012 was €3.5 million. We have performed an impairment test of goodwill as of December 31, 2013 and 2012, and our date of transition of January 1, 2012. No impairment losses have been recognized.

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

We review the estimated useful lives of property, plant and equipment and finite-lived intangible assets at the end of each reporting period. We have concluded that the useful lives applied for 2013 and 2012 are appropriate.

Except for the above areas, assumptions and estimates are not considered to be critical to the consolidated financial statements. No estimates or judgments have been made involving a material risk of significant adjustments of the assets or liabilities at the balance sheet date.

Note 3—Revenue

	Consolidated	
	2013	2012
	(EUR'000)	
Revenue from the rendering of services	4,161	5,191
License income	16,247	10,392
Total revenue	20,408	15,583
Revenue from external customers (geographical)		
USA	10,965	4,708
Germany	9,443	10,875
Total revenue	20,408	15,583

Note 4—Segment Information

We are managed and operated as one business unit. No separate business areas or separate business units have been identified in relation to product candidates or geographical markets. Accordingly, we do not disclose information on business segments or geographical markets, except for the geographical information on revenue included in Note 3 and the information regarding major customers included below.

In the consolidated financial statements for 2013, three single customers each account for more than 10% of total revenue. The revenue from each customer amounts to €9.4 million (46%); €7.4 million (36%); and €3.6 million (18%), respectively.

In the consolidated financial statements for 2012, two single customers each account for more than 10% of total revenue. The revenue from each customer amounts to €10.5 million (67%); and €3.6 million (23%), respectively.

Note 5—Staff Cost

	Consolidated	
	2013	2012
	(EUR'000)	
Wages and salaries	4,773	3,739
Share-based payment	671	124
Pension costs	35	28
Social security costs	427	350
Total salary expenses	5,906	4,241
Compensation to Key Management Personnel		
Wages and salaries	497	496
Share-based payment	251	108
Social security costs	37	24
Total compensation to Key Management Personnel	785	628
Average number of employees	45	38

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, 2013, our board of directors has been authorized to grant up to 613,746 warrants to our employees, board members and select consultants without preemptive subscription rights for the shareholders of Ascendis Pharma A/S. As of December 31, 2013, 531,075 warrants had been granted. Each warrant carries the right to subscribe for one ordinary A share of a nominal value of DKK 1. The exercise price is fixed at the fair market value of our ordinary shares at the time of grant as determined by our board of directors. The exercise prices under our warrant programs are €10.59 and €31.98 depending on the grant dates. The periods in which the outstanding warrants can be exercised include January 1 to January 21 and August 1 to August 21 in each year until 2015 for the first program and until 2023 for the second program. Apart from exercise prices and exercise periods, the programs are similar.

Vesting Conditions

Warrants issued during the period from 2008 to 2012 generally vest over 36 months with 1/36 of the warrants vesting per month from the date of grant. However, some warrants are subject to shorter vesting periods, to a minimum of 24 months.

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.

Warrants generally cease to vest from the date of termination in the event that (i) the warrant holder terminates the employment contract and the termination is not a result of breach of the employment terms by us, or (ii) in the event that we terminate the employment contract and the warrant holder has given us good reason to do so. The warrant holder will, however, be entitled to exercise vested warrants in the first exercise period after termination.

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 two exercise periods of three weeks, each commencing on January 1 and August 1, respectively. The last exercise period for warrants granted during the period from 2008 to 2012 expires in August 2015, and the last exercise period for warrants granted in December 2012 or later expires in August 2023. Warrants not exercised by the warrant holder during the last exercise period shall become null and void without further notice or compensation or payment of any kind to the warrant holder.

If the warrant holder is a consultant, advisor or board member, the exercise of warrants is conditional upon the warrant holder'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 warrant holder's actions or omissions, the warrant holder shall be entitled to exercise vested warrants in the pre-defined exercise periods.

Adjustments

Warrant holders are entitled to an adjustment of the number of warrants issued and/or the exercise price applicable in the event of certain changes to the share capital of Ascendis Pharma A/S at a price other than the

market price and in the event of payments of dividends in a given year in excess of 10% of the equity of Ascendis Pharma A/S.

Warrant Activity

The following table specifies the warrant activity during the year:

	Total Warrants	Weighted Average Exercise Price EUR
Outstanding at January 1, 2012	295,952	11.64
Granted during the year	189,151	31.98
Exercised during the year	—	—
Forfeited during the year	—	—
Expired during the year	—	—
Outstanding at December 31, 2012	485,103	19.57
Granted during the year	45,972	31.98
Exercised during the year	—	—
Forfeited during the year	—	—
Expired during the year	—	—
Outstanding at December 31, 2013	531,075	20.65
Vested at the balance sheet date	347,742	11.34

As of December 31, 2013, a total of 531,075 warrants were outstanding with a weighted average exercise price of €20.65. 347,742 of these warrants had vested as of December 31, 2013. For comparison, as of December 31, 2012, a total of 485,103 warrants were outstanding with a weighted average exercise price of €19.57. 289,306 of these warrants had vested as of December 31, 2012.

Warrant Compensation Costs

Warrant compensation costs are determined with basis in the grant date fair value of the warrants granted and recognized over the vesting period. Fair value of the warrants is calculated at the grant dates by use of the Black-Scholes Option Pricing model with the following assumptions: (1) an exercise price equal to or above the estimated market price of our shares at the date of grant; (2) an expected lifetime of the warrants determined as a weighted average of the time from grant date to date of becoming exercisable and from grant date to expiry of the warrants; (3) a risk free interest rate equaling the effective interest rate on a Danish government bond with the same lifetime as the warrants; (4) no payment of dividends; and (5) a volatility for comparable companies for a historic period equaling the expected lifetime of the warrants. The expected volatility reflects the assumption that the historical volatility over a period similar to the life of the warrants is indicative of future trends. The expected volatility has been calculated using a simple average of daily historical data of comparable publicly traded companies.

The following table summarizes the input to the Black-Scholes Option Pricing model for warrant grants in 2013 and 2012:

	2013	2012
Expected volatility	63 - 68%	67 - 70%
Risk-free interest rate	0.78 - 1.51%	0.08 - 0.60%
Expected life of warrants (years)	4.92 - 7.43	2.87 - 7.43
Weighted average calculated share price	EUR 13.22 - 29.80	EUR 13.22
Fair value of warrants granted in the year	<u>EUR 5.17 - 18.73</u>	<u>EUR 2.63 - 6.41</u>

Warrant compensation cost is recognized in the profit/loss statement over the vesting period of the warrants granted.

	Consolidated	
	2013	2012
	(EUR'000)	
Research and development costs	545	124
General and administrative expenses	126	0
Total warrant compensation costs	<u>671</u>	<u>124</u>

Value of Outstanding Warrants

For the year ended December 31, 2013, the aggregate value of outstanding warrants has been calculated at €9.8 million using the Black-Scholes Option Pricing model. The following table specifies the weighted average exercise price and the weighted average life of outstanding warrants:

	Year of Grant	Number of Warrants	Weighted Average Exercise Price EUR	Weighted Average Life (months)
Granted in September	2008	155,970	10.59	20-21
Granted in March and December	2009	125,482	10.59	20-21
Granted in December	2011	14,500	31.98	20-21
Granted in October and December	2012	189,151	31.98	20-117
Granted in March, June, September and December	2013	45,972	31.98	115-117
Outstanding at December 31, 2013		<u>531,075</u>	<u>20.65</u>	<u>50-60</u>
Vested at the balance sheet date		<u>347,742</u>	<u>11.34</u>	

For comparison, as at December 31, 2012, a total of 485,103 warrants were outstanding with a weighted average exercise price of €19.57 and weighted average life of 50 to 60 months:

	Year of Grant	Number of Warrants	Weighted Average Exercise Price EUR	Weighted Average Life (months)
Granted in September	2008	155,970	10.59	20-21
Granted in March and December	2009	125,482	10.59	20-21
Granted in December	2011	14,500	31.98	20-21
Granted in October and December	2012	189,151	31.98	20-117
Outstanding at December 31, 2012		<u>485,103</u>	<u>19.57</u>	<u>50-60</u>
Vested at the balance sheet date		<u>289,309</u>	<u>10.59</u>	

Note 6—Finance Income and Finance Expenses

	Consolidated	
	2013	2012
	(EUR'000)	
Exchange rate gains	158	4
Total finance income	158	4
Interest expense	(8)	(20)
Exchange rate losses	(724)	(212)
Total finance expenses	(732)	(232)

Note 7—Tax on Profit/Loss for the Year and Deferred Tax

	Consolidated	
	2013	2012
	(EUR'000)	
Tax on profit for the year:		
Current tax	626	35
Change of deferred tax	—	—
	626	35
Tax for the year can be explained as follows:		
Profit before tax	4,705	1,285
Tax at the Danish corporation tax rate of 25%	1,176	321
Tax effect of:		
Non-deductible costs	173	43
Other effects	97	10
Change in unrecognized deferred tax assets	(820)	(339)
Tax on profit for the year	626	35
Unrecognized deferred tax asset:		
Tax deductible losses	(2,345)	(3,227)
Deferred income	(4,367)	(4,271)
Other temporary differences	(120)	(155)
Unrecognized deferred tax asset	(6,832)	(7,653)

The deferred tax assets have not been recognized in the statement of financial position due to uncertainty relating to the future utilization. The deferred tax asset can be carried forward without timing limitations. Limitations on amounts to be used each year exist.

Note 8—Intangible Assets

	Consolidated		
	Acquired Intellectual Property Rights	Goodwill	Total
	(EUR'000)		
Cost:			
At January 1, 2012	—	3,495	3,495
Disposals	—	—	—
December 31, 2012	—	3,495	3,495
Additions	—	—	—
December 31, 2013	—	3,495	3,495
Accumulated amortization:			
At January 1, 2012	—	—	—
Amortization charge	—	—	—
Disposals	—	—	—
December 31, 2012	—	—	—
Amortization charge	—	—	—
At December 31, 2013	—	—	—
Carrying amount:			
At December 31, 2013	—	3,495	3,495
At December 31, 2012	—	3,495	3,495
At January 1, 2012	—	3,495	3,495

Goodwill relates to the acquisition of Complex Biosystems GmbH (now Ascendis Pharma GmbH) in 2007. Goodwill was calculated as the excess amount of the purchase price to the fair value of identifiable assets acquired, and liabilities assumed at the acquisition date. Business combinations recognized before January 1, 2012 have not been adjusted to IFRS 3, “Business Combinations”. Ascendis Pharma GmbH was initially a separate technology platform company, but is now an integral part of our research and development activities, including significant participation in the development services provided to our external collaboration partners. Accordingly, it is not possible to look separately at Ascendis Pharma GmbH when considering the recoverable amount of the goodwill. Goodwill is considered on a consolidated level as we are considered to represent one cash-generating unit. The recoverable amount of the cash-generating unit is determined based on an estimation of the company’s fair value less costs of disposal. We have determined the fair value of goodwill after taking into account the results of a third party valuation of our group enterprises as of the balance sheet dates. The computation of our enterprise value exceeded the carrying amount of our equity, leaving sufficient value to cover the carrying amount of goodwill. The valuation methodology applied was based on a combination of a market approach, an option pricing method and a probability-weighted expected return method.

The market approach was based on market multiples of nine comparable publicly traded companies in the same industry or similar lines of business. The multiples and values were applied to our corresponding financial metrics, as well as used for input to the option pricing method.

Under the probability-weighted expected return method, the value of the various equity securities were estimated based upon an analysis of our future value, assuming various future outcomes. Share value is based upon the

probability-weighted present value of expected future investment returns, considering each of our possible future outcomes, as well as the rights of each share class.

Goodwill is tested for impairment on a yearly basis at December 31, or more frequently, if indications of impairment are identified.

Note 9—Property, Plant and Equipment

	Consolidated		
	Plant and Machinery	Other Equipment (EUR'000)	Leasehold Improve- ments
Cost:			
At January 1, 2012	1,876	466	248
Additions	190	83	18
December 31, 2012	2,066	549	266
Additions	830	214	151
Disposals	—	(26)	—
At December 31, 2013	2,896	737	417
Accumulated depreciation:			
At January 1, 2012	(971)	(256)	(46)
Depreciation charge	(318)	(80)	(27)
December 31, 2012	(1,289)	(336)	(73)
Depreciation charge	(277)	(94)	(34)
Disposals	—	26	—
At December 31, 2013	(1,566)	(404)	(107)
Carrying amount:			
At December 31, 2013	1,330	333	310
At December 31, 2012	777	214	193
At January 1, 2012	905	210	202
Carrying Amount of assets held under Finance Leases:			
At December 31, 2013	—	—	—
At December 31, 2012	46	—	—
At January 1, 2012	194	—	—
		Consolidated	
		2013	2012
		(EUR'000)	
Depreciation charges are recognized as:			
Research and development costs		(401)	(415)
General and administrative expenses		(4)	(10)
Total depreciation charges		(405)	(425)

Note 10—Investments in Group Enterprises

Investments in Group enterprises comprise:

<u>Company</u>	<u>Domicile</u>	<u>Ownership</u>
Ascendis Pharma GmbH	Germany	100%
Ascendis Pharma, Inc.	US	100%
Ascendis Pharma, Ophthalmology Division A/S	Denmark	100%
Ascendis Pharma, Growth Disorders Division A/S	Denmark	100%
Ascendis Pharma, Osteoarthritis Division A/S	Denmark	100%
Ascendis Pharma, Relaxin Division A/S	Denmark	100%

Note 11—Share Capital

The share capital of Ascendis Pharma A/S consists of 2,700,487 shares at a nominal value of DKK 1, split into the following share classes:

	<u>Number of Shares</u>	<u>Nominal value per share DKK</u>	<u>Nominal value per share DKK</u>
Ordinary A shares	323,425	1	323,425
Preference B shares	274,983	1	274,983
Preference C shares	<u>2,102,079</u>	1	<u>2,102,079</u>
Total	<u>2,700,487</u>		<u>2,700,487</u>

In case of a sale, liquidation, bankruptcy or other dissolution of Ascendis Pharma A/S or, in the event of distribution of dividends or any other distribution from Ascendis Pharma A/S to its shareholders, the proceeds shall be distributed in the following order, until the proceeds are exhausted:

First, the holders of preference C shares will be entitled to receive an amount per preference C share corresponding to the subscription price paid per preference C share as adjusted for dividend payments, share splits, recapitalizations and similar events.

Second, the holders of preference B shares will be entitled to receive an amount per preference B share corresponding to the subscription price paid per preference B share as adjusted for dividend payments, share splits, recapitalizations and similar events.

Third, the holders of the ordinary A shares will be entitled to receive an aggregate amount of €400 thousand to be divided between the holders of ordinary A shares on a pro rata basis.

The balance, if any, will be distributed among all shareholders on a pro rata basis.

Any merger or acquisition resulting in a change of control of Ascendis Pharma A/S, or sale of all or substantially all of its assets, or reorganization or other transaction in which there is a change of control of Ascendis Pharma A/S shall be treated as a liquidation for purposes of the liquidation preferences.

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Notes to the Consolidated Financial Statements

The number of shares of the Company are as follows:

	2013	2012	2011	2010	2009
Changes in share capital					
Beginning of year	2,700,487	2,700,487	2,526,390	2,272,727	2,272,727
Increase through conversion of debt	—	—	174,097	253,663	—
End of year	<u>2,700,487</u>	<u>2,700,487</u>	<u>2,700,487</u>	<u>2,526,390</u>	<u>2,272,727</u>

Note 12—Other Reserves**Foreign Currency Translation Reserve**

Exchange differences relating to the translation of the results and net assets of our foreign operations from their functional currencies to our presentation currency are recognized directly in other comprehensive income and accumulated in the foreign currency translation reserve. At conversion to IFRS, the cumulative translation differences for all foreign operations were deemed to be zero at the date of transition to IFRS, January 1, 2012. Subsequent to the date of transition to IFRS, exchange differences previously accumulated in the foreign currency translation reserve are reclassified to profit or loss on the disposal of the foreign operation, excluding translation differences that arose before the date of transition to IFRS.

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 5.

	Consolidated		Total
	Foreign currency translation reserve	Share- based payment reserve	
At January 1, 2012	—	1,980	1,980
Other comprehensive income for the year, net of tax	(51)	—	(51)
Share-based payment	—	124	124
December 31, 2012	(51)	2,105	2,054
Other comprehensive income for the year, net of tax	(6)	—	(6)
Share-based payment	—	671	671
At December 31, 2013	(57)	2,776	2,719

Note 13—Deferred Income

We enter into collaboration agreements which are considered to include multiple elements for revenue recognition purposes. Typically, the collaboration agreements include patent transfers, licenses to our technology platform, development activities and other services related to the development of new products. The elements included in the collaboration agreements typically are inseparable and the payments received from the collaboration partners do not necessarily match the individual deliverables with respect to timing and amount. Accounting for such revenue generating transactions under IAS 18 requires that any consideration received before satisfaction of all criteria for revenue recognition be recognized as deferred income in the balance sheet and recognized as revenue in the income statement as the criteria for revenue recognition are satisfied.

Deferred income can be specified as follows:

	Consolidated	
	2013	2012
	(EUR'000)	
Up-front payments for collaboration agreements	17,470	21,084
Total deferred income	17,470	21,084

Note 14—Commitments and Contingencies

Operating Leases

We operate from leased premises in Denmark, Germany and the US. In addition, we have entered into operating leases for equipment. The total lease commitment under operating leases was:

	Consolidated	
	2013	2012
	(EUR'000)	
Within 1 year	577	436
Within 1 to 5 years	138	361
After 5 years	—	—
Total commitments held under operating leases	715	797

Finance Leases

In 2013, we paid the last installment on a lease agreement for laboratory equipment. The net book value of the equipment was €0 as of December 31, 2013 and €46 thousand as of December 31, 2012.

We paid €220 thousand in installments for the year ended December 31, 2013, and €213 thousand for the year ended December 31, 2012.

Guarantees

In 2012, we had provided a bank guarantee of €27 thousand with respect to a landlord. During 2013, the bank guarantee was terminated in connection with a renegotiation of the lease agreement.

Note 15—Financial Risk Management and Financial Instruments

Capital Management

We manage our capital to ensure that all group entities will be able to continue as going concerns while maximizing the return to shareholders through the optimization of our debt and equity balance. Our overall strategy in this regard has remained unchanged since 2012.

Our capital structure consists only of equity comprising issued capital, reserves and retained earnings. We do not hold any debt.

We are not subject to any externally imposed capital requirements.

We review our capital structure on an ongoing basis. As we do not have external debt, such review currently comprises a review of the adequacy of our capital compared to the resources required for carrying out our activities.

Financial Risk Management Objectives

We regularly monitor the access to domestic and international financial markets, manage the financial risks relating to our operations, and analyze exposures to risk, including market risk, such as currency risk and interest rate risk, credit risk and liquidity risk.

We seek to minimize the effects of these risks by managing transactions and holding positions in the various currencies used in our operations. We do not enter into or trade financial instruments for speculative purposes.

Market Risk

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

Foreign Currency Risk Management

We undertake transactions denominated in foreign currencies and, consequently, have exposures to exchange rate fluctuations arise. Exchange rate exposures are managed through maintaining positions in the various currencies used in our operations and managing payments from the most appropriate positions.

The carrying amounts of our foreign currency denominated monetary assets and liabilities at the end of the reporting period are as follows (EUR equivalents):

	Consolidated	
	2013	2012
	(EUR'000)	
Danish Kroner (DKK)	2,518	(653)
US Dollars (USD)	15,851	12,084
Euro (EUR)	375	6,713
Other	(34)	(183)
	<u>18,710</u>	<u>17,961</u>

Foreign Currency Sensitivity Analysis

We are primarily exposed to US Dollars, or USD, and Danish Kroner, or DKK. As there is an official target zone of 4.5% between DKK and EUR within which DKK can fluctuate, no significant fluctuations can occur within a short timeframe between those two currencies.

The following table details our sensitivity to a 10% increase and decrease in the EUR against the USD. 10% represents our assessment of the reasonably possible change in foreign currency rates. The sensitivity analysis includes only outstanding foreign currency denominated monetary items and adjusts their translation at the period-end for a 10% change in foreign currency rate. The sensitivity analysis includes external payables and receivables as well as balances held in foreign currencies. A positive number indicates an increase in profit or equity where the USD strengthens 10% against the relevant currency. For a 10% weakening of EUR against

USD, there would be a comparable impact on the profit or equity, and the balances shown below would be negative.

	Consolidated	
	2013	2012
	(EUR'000)	
Profit or loss	1,585	1,208
Equity	1,585	1,208

We believe the sensitivity analysis is representative of the inherent foreign exchange risk associated with our operations.

Interest Rate Risk Management

We are not directly exposed to interest rate risk because our capital structure contains no interest bearing debt. Accordingly, no interest sensitivity analysis has been presented.

Credit Risk Management

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss. We consider all of our material counterparties to be creditworthy. Our exposure to credit risk is continuously monitored, in particular, if agreed payments are delayed.

While the concentration of credit risk is significant, we consider the credit risk for each of our individual customers to be low. Accordingly, we have made no provision for doubtful accounts.

The credit risk on cash and cash equivalents is limited because the counterparties are banks with high credit-ratings assigned by international credit-rating agencies. To spread our credit risk, we deposit our cash reserves with several banks.

Liquidity Risk Management

Ultimate responsibility for liquidity risk management rests with our board of directors. We manage liquidity risk by maintaining adequate reserves and banking facilities by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities.

Note 16—Related Party Transactions

Our major shareholders, the Board of Directors, the Executive Management, and other key employees are considered to be related parties as they can exercise a significant influence on our operations. Related parties also include undertakings in which such persons have significant interests. Additionally, all our group enterprises are considered related parties.

Apart from equity transactions and remuneration to the Company's Board of Directors and management as specified in Note 5, the following transactions took place between the Group and its related parties during the financial year:

	Consolidated	
	2013	2012
	(EUR'000)	
Board of Directors:		
Purchase of services	(19)	(71)
Total transactions with related parties	(19)	(71)

Except for the information disclosed above, we have not undertaken any significant transactions with members of the Board of Directors, the Executive Management or the major shareholders, or undertakings in which the identified related parties have significant interests.

Note 17—Ownership

The following shareholders are registered as holding more than 5% of the voting share capital or of the nominal value of the share capital:

- Sofinnova Capital V FCPR, France
- Gilde Healthcare II Sub-Holding B.V., The Netherlands
- Zweite TechnoStart Ventures Verwaltungs GmbH & Co. KG i.L., Germany
- Jan Møller Mikkelsen, USA

Note 18—First-time Adoption of IFRS

Effective from the financial year 2013, we present the consolidated financial statements in EUR, which is the functional currency of Ascendis Pharma A/S. Comparative figures have been translated accordingly.

Effective from the financial year 2013, we prepared and presented the consolidated financial statements in accordance with IFRS as issued by the IASB and IFRS as adopted by the EU. The effects of the transition to financial reporting under IFRS are described below.

Exemptions Used in the Transition from Previous GAAP to IFRS

IFRS 1, “First-Time Adoption of International Financial Reporting Standards” allows first-time adopters certain exemptions from the retrospective application of certain standards. We have applied the following exemptions:

IFRS 3, “Business Combinations” has not been applied to business combinations that occurred before January 1, 2012. After the date of acquisition, the measurement of the net assets acquired is based on IFRS. We did not recognize or exclude any previously recognized amounts as a result of IFRS recognition requirements. As such, Danish GAAP balances relating to business combinations entered into before January 1, 2012, including goodwill, have been carried forward without adjustments.

IAS 21, “The Effects of Changes in Foreign Exchange Rates” has not been applied to foreign operations that were formed or acquired prior to the transition to IFRS. The cumulative translation adjustment account has been reset to zero at the date of transition with a corresponding entry to retained earnings.

Changes in Functional Currency

Historically, the consolidated financial statements have been prepared under Danish GAAP with DKK being the reporting currency. In connection with the conversion to IFRS, we determined that the functional currency of Ascendis Pharma A/S was EUR and it was decided to change the presentation currency of the consolidated financial statements from DKK to EUR.

Opening IFRS Statement of Financial Position at January 1, 2012 (date of transition to IFRS)

	Notes	Consolidated		IFRS as of Jan 1, 2012
		Local GAAP	Remeasurement (EUR'000)	
Assets				
Non-current assets				
Intangible assets		3,495	—	3,495
Property, plant and equipment		1,318	—	1,318
Deposits		31	—	31
		4,844	—	4,844
Current assets				
Trade receivables		1,242	—	1,242
Other receivables		778	—	778
Prepayments		271	—	271
Cash and cash equivalents		15,683	—	15,683
		17,974	—	17,974
Total assets		22,818	—	22,818
Equity and liabilities				
Equity				
Share capital		362	—	362
Other reserves	A	—	1,980	1,980
Retained earnings/(accumulated deficit)	A,B	16,537	(18,647)	(2,109)
Total equity		16,899	(16,667)	233
Non-current liabilities				
Finance lease liabilities		213	—	213
		213	—	213
Current liabilities				
Finance lease liabilities		187	—	187
Trade payables and other payables		2,518	—	2,518
Deferred income	B	3,000	16,667	19,667
		5,705	16,667	22,372
Total liabilities		5,918	16,667	22,585
Total equity and liabilities		22,818	—	22,818

**Reconciliation of Financial Position and Equity as at December 31, 2012
(End of Most Recent Annual Financial Statements)**

	Notes	Consolidated		IFRS as of December 31, 2012
		Local GAAP	Remeasurement (EUR'000)	
Assets				
Non-current assets				
Intangible assets	C	2,904	591	3,495
Property, plant and equipment		1,184	—	1,184
Deposits		30	—	30
		4,118	591	4,709
Current assets				
Trade receivables		5,718	—	5,718
Other receivables		353	—	353
Prepayments		90	—	90
Cash and cash equivalents		14,535	—	14,535
		20,696	—	20,696
Total assets		24,814	591	25,405
Equity and liabilities				
Equity				
Share capital		362	—	362
Other reserves	A	(1)	2,055	2,054
Retained earnings/(accumulated deficit)	A,B,C,D	17,688	(18,548)	(860)
Total equity		18,049	(16,493)	1,556
Current liabilities				
Finance lease liabilities		212	—	212
Trade payables and other payables		2,532	—	2,532
Deferred income	B	4,000	17,084	21,084
Income taxes		21	—	21
		6,765	17,084	23,849
Total liabilities		6,765	17,084	23,849
Total equity and liabilities		24,814	591	25,405

**Reconciliation of Total Comprehensive Income for the Year ended December 31, 2012
(Most Recent Annual Financial Statements)**

	Notes	Consolidated		IFRS as of December 31, 2012
		Local GAAP	Remeasurement (EUR'000)	
Revenue	B	17,439	(1,856)	15,583
Research and development costs	A,B,C,D	(13,619)	2,238	(11,380)
General and administrative expenses	B	(2,690)	—	(2,690)
Other operating income	D	334	(334)	—
Operating profit		1,464	49	1,513
Finance income		4	—	4
Finance expenses		(232)	—	(232)
Profit before tax		1,236	49	1,285
Tax on profit for the year		(35)	—	(35)
Net profit for the year		1,201	49	1,250
<i>Items that may be reclassified subsequently to profit or loss:</i>				
Exchange differences on translating foreign operations		—	(51)	(51)
Other comprehensive loss for the year		—	(51)	(51)
Total comprehensive income/loss for the year		1,201	(2)	1,199

Notes to the Reconciliations from Danish GAAP to IFRS

Note A

No compensation for share-based payment transactions was recognized under Danish GAAP. As part of our conversion to IFRS, such compensation has been calculated for all historical share-based transactions in accordance with IFRS 2 and recognized in retained earnings in the IFRS opening balance. The total adjustment for historical warrant grants was approximately €2 million and €2.1 million as of January 1, 2012 and December 31, 2012, respectively, of which €1.3 million and €1.4 million were related to warrants granted to employees of our subsidiaries, respectively. Please refer to Note 5 for additional details of the assumptions used in the calculations.

Note B

As part of our conversion to IFRS, all historical revenue generating transactions were reviewed for compliance with IAS 18. Under Danish GAAP, revenue has generally been recognized at earlier stages in the revenue generating transactions, whereas IAS 18 has more specific requirements for recognition of revenue. Under Danish GAAP, revenue recognition has been focused on the legal right to payments whereas revenue recognition under IAS 18 is more focused on the interdependence of multiple deliverables, and when services have been provided and earned. Accordingly, part of the up-front payments under agreements with continued involvement that had been recognized as revenue under Danish GAAP is being deferred under IFRS. A total of €16.7 million was reclassified from revenue to deferred income in the opening balance of IFRS as of January 1, 2012 and €17.1 million as of December 31, 2012.

Please refer to Note 13 for additional details on deferred income.

Note C

Intangible assets in the consolidated financial statements comprise goodwill related to the acquisition of our German subsidiary in 2007. The acquisition under Danish GAAP resulted in recognition of goodwill which was amortized over 10 years from the acquisition date. As part of the conversion to IFRS, we have utilized the exemption in IFRS 3, thereby not applying that standard to transactions completed before the transition date to IFRS. Accordingly, we fixed the carrying amount of goodwill at the transition date to IFRS which was January 1, 2012, in the amount of €3.5 thousand and replaced the amortization with yearly impairment tests. As a result, amortization of goodwill of €591 thousand recognized in 2012 under Danish GAAP has been reversed in the conversion to IFRS.

Note D

In the consolidated financial statements under Danish GAAP, government grants were recognized as other operating income. IAS 20 accepts that government grants that are received to cover expenses incurred be recognized as a credit to the financial statement line where the related expenses are recognized. Accordingly, government grants of €334 thousand previously disclosed as other operating income in 2012 have been reclassified to research and development costs as part of the conversion to IFRS.

The most recent annual consolidated financial statements prior to conversion to IFRS did not include cash flow statements, which was in accordance with Danish GAAP.

Note 19—Subsequent Events

Termination of Collaboration Agreement with United Therapeutics

In September 2012, we entered into a collaboration agreement with United Therapeutics under which we granted United Therapeutics a license to research, develop, make and commercialize products based on the TransCon technology and prostacyclin analogs, and later expanded the license to include the drug beraprost. In May 2014, United Therapeutics filed an IND for TransCon Treprostinil, which was subsequently accepted by the FDA in June 2014. On June 30, 2014, we received a notice from United Therapeutics informing us of its intent to terminate the collaboration agreement for convenience, and we are in the process of negotiating the transition of the program back to us.

Approval of the Consolidated Financial Statements

These consolidated financial statements were approved by our board of directors on August 1, 2014.

Shares



Ascendis Pharma A/S

Ordinary Shares

Prospectus
, 2014

PART II

Information Not Required in Prospectus

Item 6. Indemnification of Directors and Officers.

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 intend to enter into agreements with our board members and members of our senior management, pursuant to which, subject to limited exceptions, we will agree 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.

The form of underwriting agreement to be filed as Exhibit 1.1 to this registration statement will also provide for indemnification of us and our directors and officers upon the terms and subject to the conditions specified therein.

Item 7. Recent Sales of Unregistered Securities.

The following list sets forth information as to all securities we have sold since January 1, 2011, which were not registered under the Securities Act.

1. In May 2011, we issued an aggregate of 174,097 shares of our preference C shares at a price of €31.9847 per share. All shares were issued in exchange for the conversion of our convertible promissory notes. The aggregate gross consideration received for these issuances was €5.6 million.
2. We granted warrants to employees, directors and consultants under our Warrant Incentive Program covering an aggregate of 331,773 ordinary shares, at a weighted-average exercise price of €31.9847 per share.

The transactions described in paragraph (1) were made outside the United States pursuant to Regulation S or to U.S. persons pursuant to Section 4(a)(2) of the Securities Act as transactions not involving any public offering and outside the United States.

The transactions described in paragraphs (2) were made outside the United States pursuant to Regulation S or to U.S. persons pursuant to Rule 701 promulgated under the Securities Act, in that the securities were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701 or to U.S. persons pursuant to Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering.

Item 8. Exhibits and Financial Statement Schedules.

(a) Exhibits. See the Exhibit Index attached to this registration statement, which is incorporated by reference herein.

(b) Financial Statement Schedules. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto.

Item 9. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.
2. For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form F-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Hellerup, Denmark, on _____, 2014.

ASCENDIS PHARMA A/S

By: _____
Jan Møller Mikkelsen
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Jan Møller Mikkelsen, Thomas P. Soloway and Michael Wolff Jensen, and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Registration Statement, including post-effective amendments or any abbreviated registration statement and any amendments thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Jan Møller Mikkelsen	President, Chief Executive Officer, Board Member and Executive Director <i>(Principal Executive Officer)</i>	
_____ Thomas P. Soloway	Senior Vice President, Chief Financial Officer and Executive Director <i>(Principal Financial Officer)</i>	
_____ Peter Rasmussen	Vice President, Finance <i>(Principal Accounting Officer)</i>	
_____ Michael Wolff Jensen, L.L.M.	Chairman of the Board of Directors	
_____ Rafaèle Tordjman, M.D., Ph.D.	Board Member	
_____ Edwin de Graaf	Board Member	
_____ Michael Mayer	Board Member	
_____ Martin Olin	Board Member	

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Ascendis Pharma, Inc.

Authorized Representative in the
United States

By: _____

Name: Thomas P. Soloway
Title: Senior Vice President,
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Provided Herewith
		Form	Date	Number	
1.1*	Form of Underwriting Agreement.				
3.1	Articles of Association, currently in effect.				X
3.2*	Form of Amended and Restated Articles of Association, effecting a share split, to be in effect prior to the closing of this offering.				
3.3*	Form of Amended and Restated Articles of Association, to be in effect following the closing of this offering.				
4.1	Reference is made to exhibits 3.1 through 3.3.				
5.1*	Opinion of Mazanti-Andersen Korsø Jensen.				
8.1*	Tax opinion of Mazanti-Andersen Korsø Jensen.				
10.1†	Exclusive Licence Agreement dated July 31, 2013 between Ascendis Pharma Ophthalmology Division A/S, Genentech, Inc. and F. Hoffmann-La Roche Ltd.				X
10.2†	Patent Transfer & Exclusive Licence Agreement dated December 15, 2010 between Ascendis Pharma A/S and Sanofi Aventis Deutschland GmbH.				X
10.3*	English language summary of Rental Agreement, between Technologiepark Heidelberg II GmbH & Co. KG and Ascendis Pharma GmbH.				
10.4(a)#	Reference is made to exhibits 3.1 through 3.3.				
10.4(b)#	Form of Warrant Certificate.				X
10.5#*	Form of Indemnification Agreement for board members and senior management.				
21.1	List of Subsidiaries.				X
23.1*	Consent of independent registered public accounting firm.				
23.2*	Consent of Mazanti-Andersen Korsø Jensen (included in Exhibit 5.1).				
23.3*	Consent of Mazanti-Andersen Korsø Jensen (included in Exhibit 8.1).				
24.1*	Power of Attorney. Reference is made to the signature page to the Registration Statement.				

* To be filed by amendment.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

Indicates senior management contract or compensatory plan.

19 June 2014

Articles of Association

of

Ascendis Pharma A/S

(Registration no 29918791)

Name, Registered Office and Objects of the Company:

Article 1

The company's name is Ascendis Pharma A/S.

Article 2

The Company's registered office is situated in Gentofte Municipality.

Article 3

The object of the company 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.

Article 4

The share capital of the Company is DKK 2,700,487 divided into shares of DKK 1 each and multiples thereof. The share capital is fully paid up and is divided into nominal DKK 323,425 A-shares, nominal DKK 274,983 B-shares and nominal DKK 2,102,079 C-shares

The law firm of Mazanti-Andersen, Korsø Jensen & Partnere, St. Kongensgade 69, 1264 Copenhagen K. shall keep and maintain the company's register of owners.

Article 4a

The board of directors is authorised at one or more times within the period until 3 December 2014 to issue 521 warrants to the company's and its subsidiaries' employees, management, board members, consultants and advisors of the company without pre-emptive subscription rights for the company's shareholders. Each warrant carries the right to subscribe for 1 A-share of a nominal value of DKK 1.

Other terms and conditions of the warrants issued under the authorization, including any remuneration hereof, exercise periods, subscription price, adjustments caused by changes of the company's situation etc., shall be fixed by the Board of Directors.

The Board of Directors is authorised to increase the company's share capital within the period until 3 December 2014 at one or several times by up to nominal DKK 521 by payment in cash in order to complete the capital increase connected with the exercise of warrants.

The Board of Directors is entitled to make such amendments to the company's Articles of Association, which are necessary as a result of issuance or exercise of warrants as provided hereunder.

Article 4b

On 10 September 2008 the Board of Directors resolved to exercise the authorisation under article 4a hereof to issue 155,970 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 500 and maximum nominal DKK 155,970. The authorisation under article 4a hereof is therefore reduced from a denomination of 227,273 to a denomination of 71,303. The terms and conditions of the issued warrants have been adopted as Exhibit 1 to the articles of association and shall form an integral part hereof. The exercise price has been determined to DKK 78.9962 and 1 warrant therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 78.9962 (€10.5930 calculated on the basis of the exchange rate in effect on 10 September 2008 being 1€=DKK 7.4574).

The warrants vest by 1/36 per month from 1 January 2008 with respect to 94,375 warrants, by 1/36 per month from 1 February 2008 with respect to 1,500 warrants, by 1/36 per month from 1 May 2008 with respect to 1,500 warrants, by 1/36 per month from 1 June 2008 with respect to 1,500 warrants, by 1/36 per month from 16 May 2008 with respect to 1,500 warrants, by 1/36 per month from 1 July 2008 with respect to 2,000 warrants, by 1/36 per month from 1 September 2008 with respect to 500 warrants, by 1/36 per month from 1 April 2008 with respect to 7,588 warrants, by 1/36 per month from 14 April 2008 with respect to 34,144 warrants and by 1/24 per month from 1 September 2008 with respect to 11,636 warrants.

On 19 March 2009 the Board of Directors resolved to exercise the authorisation under article 4a hereof to issue 82,755 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 500 and maximum nominal DKK 82,755. The authorisation under article 4a hereof is therefore reduced from a denomination of 126,710 to a denomination of 43,955. The terms and conditions of the issued warrants have been adopted as Exhibit 1 to the articles of association and shall form an integral part hereof. The exercise price has been determined to DKK 78.9327 and 1 warrant therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 78.9327 (€10.5930 calculated on the basis of the exchange rate in effect on 19 March 2009 being 1€=DKK 7.4514).

The warrants vest by 1/36 per month from 10 December 2009 with respect to 58,528 warrants, by 1/36 per month from 19 March 2009 with respect to 1,500 warrants and by 1/24 per month from 19 March 2009 with respect to 22,727 warrants.

On December 9, 2009 the Board of Directors resolved to exercise the authorization under article 4a hereof to issue 42,727 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 500 and maximum nominal DKK 42,727. The authorization under article 4a hereof is therefore reduced from a denomination of 43,955 to a denomination of 1,228. The terms and conditions of the issued warrants have been adopted as Exhibit 1 to the articles of association and shall form an integral part hereof. The exercise price has been determined to € 10.5930 and 1 warrant therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 78.8289 (€10.5930 calculated on the basis of the exchange rate in effect on 9 December 2009 being 1€=DKK 7.4516).

The warrants vest by 1/36 per month from September 16, 2009 with respect to 7,500 warrants, with 1/36 per month from December 9, 2009 with respect to 23,863 warrants and by 1/24 per month from December 9, 2009 with respect to 11,364 warrants

On December 13, 2011 the Board of Directors resolved to exercise the authorization under article 4a hereof to issue 14,500 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 500 and maximum nominal DKK 14,500. The authorization under article 4a hereof is therefore reduced from a denomination of 51,228 to a denomination of 36,728. The terms and conditions of the issued warrants have been adopted as Exhibit 1 to the articles of association and shall form an integral part hereof. The exercise price has been determined to € 31.9847 and 1 warrant therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 237.8574 (€31.9847 calculated on the basis of the exchange rate in effect on 13 December 2011 being 1€=DKK 7.4366).

The warrants vest by 1/36 per month from December 13, 2011.

On October 8, 2012 the Board of Directors resolved to exercise the authorization under article 4a hereof to issue 16,500 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 500 and maximum nominal DKK 16,500. The authorization under article 4a hereof is therefore reduced from a denomination of 36,728 to a denomination of 20,228. The terms and conditions of the issued warrants have been adopted as Exhibit 1 to the articles of association and shall form an integral part hereof. The exercise price has been determined to € 31.9847 and 1 warrant therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 238.5067 (€31.9847 calculated on the basis of the exchange rate in effect on 8 October 2012 being 1€=DKK 7.4569).

The warrants vest by 1/36 per month from October 8, 2012.

On December 3, 2012 the Board of Directors resolved to exercise the authorization under article 4a hereof to issue 172,651 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 100 and maximum nominal DKK 172,651. The authorization under article 4a hereof is therefore reduced from a denomination of 301,294 to a denomination of 128,643. The terms and conditions of the issued warrants have been adopted as Exhibit 2 to the articles of association and shall form an integral part hereof. The exercise price has been determined to € 31.9847 and 1 warrant therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 238.6123 (€31.9847 calculated on the basis of the exchange rate in effect on 3 December 2012 being 1€=DKK 7.4602).

The warrants vest by 1/48 per month from December 3, 2012 with respect to 166,297 warrants and by 1/48 per month from October 1, 2012 with respect to 6,354 warrants.

On March 19, 2013 the Board of Directors resolved to exercise the authorization under article 4a hereof to issue 7,100 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 100 and maximum nominal DKK 7,100. The authorization under article 4a hereof is therefore reduced from a denomination of 128,643 to a denomination of 121,543. The terms and conditions of the issued warrants have been adopted as Exhibit 2 to the articles of association and shall form an integral part hereof. The exercise price has been determined to € 31.9847 and 1 warrant therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 238.6027 (€31.9847 calculated on the basis of the exchange rate in effect on 19 March 2013 being 1€=DKK 7.4599).

The warrants vest by 1/48 per month from March 19, 2013.

On June 27, 2013 the Board of Directors resolved to exercise the authorization under article 4a hereof to issue 21,872 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 100 and maximum nominal DKK 21,872. The authorization under article 4a hereof is therefore reduced from a denomination of 121,543 to a denomination of 99,671. The terms and conditions of the issued warrants have been adopted as Exhibit 2 to the articles of association and shall form an integral part hereof. The exercise price has been determined to € 31.9847 and 1 warrant therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 238.5835 (€31.9847 calculated on the basis of the exchange rate in effect on 27 June 2013 being 1€=DKK 7.4593).

The warrants vest by 1/48 per month from June 27, 2013.

On September 24, 2013 the Board of Directors resolved to exercise the authorization under article 4a hereof to issue 14,000 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 100 and maximum nominal DKK 14,000. The authorization under article 4a hereof is therefore reduced from a denomination of 99,671 to a denomination of 85,671. The terms and conditions of the issued warrants have been adopted as Exhibit 2 to the articles of association and shall form an integral part hereof. The exercise price has been determined to € 31.9847 and 1 warrant

therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 238.5131 (€31.9847 calculated on the basis of the exchange rate in effect on 24 September 2013 being 1€=DKK 7.4571).

The warrants vest by 1/48 per month from September 24, 2013.

On December 5, 2013 the Board of Directors resolved to exercise the authorization under article 4a hereof to issue 3,000 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 100 and maximum nominal DKK 3,000. The authorization under article 4a hereof is therefore reduced from a denomination of 85,671 to a denomination of 82,671. The terms and conditions of the issued warrants have been adopted as Exhibit 2 to the articles of association and shall form an integral part hereof. The exercise price has been determined to € 31.9847 and 1 warrant therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 238.5931 (€31.9847 calculated on the basis of the exchange rate in effect on 5 December 2013 being 1€=DKK 7.4596).

The warrants vest by 1/48 per month from December 5, 2013.

On January 16, 2014 the Board of Directors resolved to exercise the authorization under article 4a hereof to issue 33,148 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 100 and maximum nominal DKK 33,148. The authorization under article 4a hereof is therefore reduced from a denomination of 82,671 to a denomination of 49,523. The terms and conditions of the issued warrants have been adopted as Exhibit 2 to the articles of association and shall form an integral part hereof. The exercise price has been determined to € 31.9847 and 1 warrant therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 238.6698 (€31.9847 calculated on the basis of the exchange rate in effect on 16 January 2014 being 1€=DKK 7.4620).

The warrants vest by 1/48 per month from January 16, 2014.

On March 6, 2014 the Board of Directors resolved to exercise the authorization under article 4a hereof to issue 7,000 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 100 and maximum nominal DKK 7,000. The authorization under article 4a hereof is therefore reduced from a denomination of 49,523 to a denomination of 42,523. The terms and conditions of the issued warrants have been adopted as Exhibit 2 to the articles of association and shall form an integral part hereof. The exercise price has been determined to € 31.9847 and 1 warrant

therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 238.6922 (€31.9847 calculated on the basis of the exchange rate in effect on 6 March 2014 being 1€=DKK 7.4627).

The warrants vest by 1/48 per month from March 6, 2014.

On June 19, 2014 the Board of Directors resolved to exercise the authorization under article 4a hereof to issue 42,002 warrants and resolved simultaneously, at one or more times, to increase the share capital with minimum nominal DKK 100 and maximum nominal DKK 42,002. The authorization under article 4a hereof is therefore reduced from a denomination of 42,523 to a denomination of 521. The terms and conditions of the issued warrants have been adopted as Exhibit 2 to the articles of association and shall form an integral part hereof. The exercise price has been determined to € 31.9847 and 1 warrant therefore confers the right to subscribe nominal DKK 1 A-share against cash contribution of DKK 238.4907 (€31.9847 calculated on the basis of the exchange rate in effect on 19 June 2014 being 1€=DKK 7.4564).

The warrants vest by 1/48 per month from June 19, 2014.

Article 5

The company's shares shall be issued in name and recorded in the company's register of owners.

The company's shares are non-negotiable instruments.

No shareholder shall be obligated to have his shares redeemed in whole or in part by the company or others.

Unless requested by any shareholder, no share certificates shall be issued.

For the shares the following shall additionally apply:

In the event of a sale, liquidation, bankruptcy or other dissolution of the Company or in the event of distribution of dividends or any other distribution from the Company to the Shareholders, the proceeds shall be distributed in the following order, until the proceeds are exhausted:

- First, the holders of Preference C Shares will be entitled to receive an amount per Preference C Share corresponding to the subscription price paid per Preference C Share as adjusted for dividend payments, share splits, recapitalisations and similar events;
- Second, the holders of the Preference B Shares will be entitled to receive an amount per Preference B Share corresponding to the subscription price paid per Preference B Share as adjusted for dividend payments, share splits, recapitalisations and similar events;
- Third, the holders of the Ordinary A Shares will be entitled to receive an aggregate amount of Euro 400,000 to be divided between the holders of Ordinary A Shares on a pro rata basis;
- Then the balance, if any, will be distributed among all shareholders on a pro rata basis.

Any (i) merger or acquisition resulting in a Change of Control of the Company, or (ii) sale of all or substantially all of the Company's assets, or (iii) reorganisation or other transaction in which there is a Change of Control of the Company, shall be treated as a liquidation for purposes of the liquidation preference. This does not include any prospective financing round. Change of Control shall mean any transaction or series of transactions in which the direct or indirect ownership of Shares in the Company carrying in excess of 50% of the voting rights (on an as-converted basis) is, after such transactions, effectively transferred to any third party.

Article 6

Transfer of shares shall be recorded in the company's register of owners only when written documentation of the transfer has been presented to the Board of Directors.

Article 7

The shares can be cancelled out of court in conformity with the legislation applying to non-negotiable securities, in force at any time.

General Meetings

Article 8

General meetings of the company shall be held in Greater Copenhagen. Ordinary general meetings shall be held in due time for the audited and adopted annual report to be filed with the Danish Commerce and Companies Agency before expiry of the limit stated under the Danish Company Accounts Act.

General meetings shall be convened with 2 weeks' notice at the least and 4 weeks' notice at the most by letter, fax or by email. The convening letter shall include the agenda and shall be sent to the shareholders at the address/email address recorded in the register of owners.

A chairman appointed by the Board of Directors shall preside over the general meetings. The chairman shall decide all matters regarding the legitimacy of the general meeting, the negotiations and the voting.

Article 9

The agenda of the ordinary general meeting shall include:

1. The Board of Directors' report on the company's activities during the past year
2. Presentation of annual report with auditor's report for adoption
3. Resolution on application of profits or covering of losses as per the adopted annual report
4. Election of board members
5. Election of auditor
6. Any motions from the Board of Directors or shareholders
7. Miscellaneous

Motions from shareholders to be considered at the ordinary general meeting shall be filed in writing with the company not later than 6 weeks before the ordinary general meeting is being held, unless the Board of Directors decides, that motions received later are filed with the company in due time allowing the company to include the motion at the agenda for the ordinary general meeting.

Article 10

At general meetings, each share of DKK 1 shall carry one vote.

The matters discussed at general meetings shall be adopted by a simple majority of votes unless the law or the company's Articles otherwise provide.

In case of equality of votes the motion shall be deemed annulled.

Board of Directors:

Article 11

The company shall be governed by the Board of Directors, consisting of no less than 3 and no more than 10 board members, elected by the shareholders in general meeting. The Board of Directors is elected for one year at a time.

A number of alternate board members corresponding to the number of board members may be elected. Alternate board members shall also be elected for one year at a time.

Any board member shall retire from the Board at the ordinary general meeting following immediately after his attaining the age of 70.

The Board of Directors shall elect their chairman from their own number.

The Board of Directors shall adopt its own Rules of Procedure and ensure that the company conducts its activities in conformity with the Articles of Association and the legislation in force at any time.

The Chairman shall convene board meetings whenever he finds it necessary, or when any board member or member of management so requests.

Management:

Article 12

The Board of Directors shall employ a management consisting of 1-3 members to attend to the day-to-day management of the company, and the Board shall determine the terms and conditions of the employment. The management shall perform their duties in accordance with the guidelines and directions issued by the Board of Directors.

Binding powers:

Article 13

The company shall be bound by the Chairman of the Board of Directors and one member of management jointly or by 3 (three) members of the Board of Directors.

The Board of Directors may issue individual or joint powers of procuration.

Audit:

Article 14

One state-authorized public accountant, elected by the general meeting for one year at a time, shall audit the Company's annual reports.

Accounting Year/Annual Report:

Article 15

The company's accounting year shall be the calendar year.

The company's annual report shall present a true and fair view of the company's assets and liabilities, its financial position and results.

The company's annual report and interim reports are presented in English language.

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Most recently adopted at the annual general meeting on 19 June 2014

Appendix 1 to the Articles of Association of Ascendis Pharma A/S

Pursuant to authorisation in the articles of association for Ascendis Pharma A/S, the Board of Directors has resolved that the following terms and conditions shall apply to warrants which are granted to employees, consultants, advisors and board members according to the authorisation:

1. General

- 1.1 Ascendis Pharma A/S (hereinafter “Ascendis Pharma”) has decided to introduce an incentive scheme for employees, consultants, advisors and board members in Ascendis Pharma and its subsidiaries (hereinafter collectively referred to as “Warranholders”). The scheme is based on issuance of options, also called warrants (hereinafter only referred to as “warrants”), which are not subject to payment. Where below in clause 3.3 – 3.6 and clause 4.5 -4.6 terms for vesting etc. are described as being dependant upon employment/affiliation with Ascendis Pharma, this shall be understood as a reference to the relevant subsidiary by which the Warranholders is employed/affiliated.
- 1.2 A warrant is a right, but not an obligation, during fixed periods (exercise periods) to subscribe for new ordinary A-shares in Ascendis Pharma at a price fixed in advance (the exercise price). The exercise price, which shall correspond to the market price at the date of issuance, shall be determined by the board of directors. Each warrant carries the right to subscribe for nominal DKK 1 ordinary A-share in Ascendis Pharma at the subscription price determined by the board of directors at the date of issuance.
- 1.3 Warrants will be offered to employees, consultants, advisors and board members in Ascendis Pharma and in its subsidiaries at the discretion of the Board of Directors after suggestion from the management of Ascendis Pharma A/S. The number of warrants offered to each individual shall be based on an individual evaluation of the Warranholder’s duties. It shall appear from the individual Warranholder’s warrant certificate how many warrants have been granted to the Warranholder and what the exercise price for the warrant is.

2. Granting/subscription of warrants

- 2.1 Warrantheolders who wish to subscribe the offered warrants shall sign a Warrant Certificate with this Appendix 1 attached and, to the extent required by the Board of Directors, a Shareholders Agreement regulating the relationship between the Warrantheolders and Ascendis Pharma's other shareholders.
- 2.2 The granting of warrants shall not be subject to payment from the Warrantheolders.
- 2.3 Ascendis Pharma shall keep records of granted warrants and update the records at suitable intervals.

3. Vesting

- 3.1 The warrants shall be vested with 1/36 per month from the date of grant of the warrants covered by this Appendix 1. Warrants granted to members of the board of directors and to members of Ascendis Pharma's committees shall however vest with 1/24 per month from the date of grant of the warrants covered by this Appendix 1. The board may have determined a different vesting period in its decision to issue warrants.
- 3.2 If the stipulated fraction does not amount to a whole number of warrants, the number shall be rounded down to the nearest whole number.
- 3.3 Warrants shall only be vested to the extent the Warrantheolder is employed by Ascendis Pharma, cf. however clause 3.4 to 3.6 below.
- 3.4 In the event that the Warrantheolder terminates the employment contract and the termination is not a result of breach of the employment terms by Ascendis Pharma, and in the event that Ascendis Pharma terminates the employment contract and the Warrantheolder has given Ascendis Pharma good reason to do so, then the vesting of warrants shall cease from the time the employment is terminated, meaning from the first day when the Warrantheolder is no longer entitled to salary from Ascendis Pharma, notwithstanding that the Warrantheolder has actually ceased to perform his/her duties at an earlier date. In addition hereto the Warrantheolder's right, if any, to receive warrants granted after termination of the employment shall cease.
- 3.5 In the event that the Warrantheolder terminates the employment contract and the

termination is a result of breach of the employment terms by Ascendis Pharma, or in the event that Ascendis Pharma terminates the employment contract and the Warrantholder having not given Ascendis Pharma good reason to do so, then warrants shall continue to vest as if the Warrantholder was still employed by Ascendis Pharma.

- 3.6 Should the Warrantholder materially breach the terms of the employment, the vesting of warrants shall cease from the date when the Warrantholder is dismissed due to the material breach.
- 3.7 Warrants issued to consultants, advisors and board members only vest to the extent that the consultant, advisor or board member acts on behalf of Ascendis Pharma as a consultant, advisor or board member.
- 3.8 If the Warrantholder takes leave – other than maternity leave – and the leave exceeds 60 days, the dates when the warrants shall be vested shall be postponed by a period corresponding to the duration of the leave.

4. Exercise

- 4.1 When a warrant has been vested, it may be exercised during the exercise periods. From 2010, there is two exercise periods of 2 times 3 weeks each year commencing on 1 January respectively 1 August and ending on 21 January respectively 21 August as follows:

- 1 – 21 January or 1 – 21 August 2010
- 1 – 21 January or 1 – 21 August 2011
- 1 – 21 January or 1 – 21 August 2012
- 1 – 21 January or 1 – 21 August 2013
- 1 – 21 January or 1 – 21 August 2014
- 1 – 21 January or 1 – 21 August 2015

- 4.2 If the last day of an exercise period is Saturday or Sunday, the exercise period shall also include the first weekday following the stipulated period.
- 4.3 When warrants have been vested, the Warrantholder shall be free to choose, which exercise period to apply for the vested warrants, cf. however, clause 4.5 below regarding material breach. It is, however, a condition for exercise that the Warrantholder in a given exercise period exercises warrants, which give a right to subscribe minimum nominal DKK 500 shares.

- 4.4 Warrants not exercised by the Warrantholder during the last exercise period, 1 – 21 August 2015, shall become null and void without further notice or compensation or payment of any kind to the Warrantholder.
- 4.5 The Warrantholder’s exercise of warrants is in principle conditional upon the Warrantholder being employed in Ascendis Pharma at the time when warrants are exercised. In case of termination of the employment the following shall apply:
- a. In the event that Ascendis Pharma terminates the employment contract and the Warrantholder having given Ascendis Pharma good reason to do so, the Warrantholder is only entitled to exercise the warrants vested at the time of termination. Exercise shall take place during the first coming exercise period after termination of the employment, however the Warrantholder shall always have minimum 3 months from the date of termination to decide if warrants shall be exercised. To the extent that the first coming exercise period commences within 3 months from the date of actual termination the Warrantholder shall be entitled to exercise the warrants in the exercise period following the first coming exercise period. All vested warrants not exercised by the Warrantholder according to this clause shall become null and void without further notice or compensation or payment of any kind.
 - b. In the event that the Warrantholder terminate the employment, or in the event that Ascendis Pharma terminates the employment contract and the Warrantholder have not given Ascendis Pharma good reason to do so, the Warrantholder is entitled to exercise the warrants as if the Warrantholder were still employed with Ascendis Pharma. Exercise shall take place in accordance with the general terms and conditions regarding exercise of warrants stipulated in clause 4.1 – 4.5. This provision shall apply if the employment contract is terminated due to retirement.
 - c. If the employment is terminated as a consequence of summary dismissal of the Warrantholder on grounds of material breach, all warrants not exercised at that time shall become null and void without notice or compensation. If the material breach is committed prior to the dismissal the vesting and the right to exercise warrants shall be deemed to have ceased at the time of the material breach. The Warrantholder shall in this case, after demand from Ascendis Pharma, be obligated to sell to Ascendis Pharma shares which have been

subscribed though exercise of warrants, after the date of the material breach. The shares shall be sold at a price corresponding to the subscription price paid by the Warrantholder.

d. If the employment is terminated due to the death of the Warrantholder all warrants not exercised by the Warrantholder shall become null and void. However, the Ascendis Pharma Board of Directors may grant an exemption from this provision to enable the estate of the Warrantholder to exercise the issued warrants whether they have been vested at the time of the death or not on the condition that exercise be effected during the first exercise period commencing after the death.

4.6 If the Warrantholder is a consultant, advisor or board member the exercise of warrants is in principle conditional upon the Warrantholder being connected to Ascendis Pharma in this capacity at the time when warrants are exercised. In case that the consultant's, advisor's or board member's relationship with Ascendis Pharma should cease without this being attributable to the Warrantholder's actions or omissions the Warrantholder shall be entitled to exercise vested warrants in the exercise periods set forth in clause 4.1 above.

4.7 Ascendis Pharma's board of directors is in the event of a listing of the company's shares on a stock exchange entitled at its discretion to change the exercise periods in order to coordinate these with applicable rules for insider trading. Unless the Board of Directors resolves otherwise the exercise periods shall in the event of a listing be changed to two 21 day periods after respectively the annual report notification and the interim report (six months).

5. **Adjustment of warrants**

5.1 Changes in Ascendis Pharma's capital structure causing a change of the potential possibility of gain attached to a warrant shall require an adjustment of the warrants.

5.2 Adjustments shall be made so that the potential possibility of gain attached to a warrant, in so far as possible, shall remain the same before and after the occurrence of an incident causing the adjustment. The adjustment shall be carried out with the assistance of Ascendis Pharma's external advisor. The adjustment may be effected either by increase or reduction of the number of shares that can be issued following exercise of a warrant and/or an increase or reduction of the exercise price.

5.3 Warrants shall not be adjusted as a result of Ascendis Pharma's issue of employee shares, share options and/or warrants as part of employee share option schemes (including options to Directors, advisors and consultants) as well as future exercise of such options and/or warrants. Warrants shall, furthermore, not be adjusted as a result of capital increases following the Warrantheolders' and others' exercise of warrants in Ascendis Pharma.

5.4 Bonus shares

If it is decided to issue bonus shares in Ascendis Pharma, warrants shall be adjusted as follows:

The exercise price for each warrant not yet exercised shall be multiplied by the factor:

$$a = \frac{A}{(A + B)}$$

and the number of warrants not yet exercised shall be multiplied by the factor:

$$\frac{1}{a}$$

where:

A = the nominal share capital before issue of bonus shares, and

B = the total nominal value of bonus shares.

If the adjusted exercise price and/or the adjusted number of shares does not amount to whole numbers, each number shall be rounded down to the nearest whole number.

5.5 Changes of capital at a price different from the market price:

If it is decided to increase or reduce the share capital in Ascendis Pharma at a price below the market price (in relation to capital decreases also above the market price), warrants shall be adjusted as follows:

The exercise price for each non-exercised warrant shall be multiplied by the factor:

$$a = \frac{(A \times K) + (B \times T)}{(A + B) \times K}$$

and the number of non-exercised warrants shall be multiplied by the factor:

$$\frac{1}{a}$$

where:

A = nominal share capital before the change in capital

B = nominal change in the share capital

K = market price / closing price of the share on the day prior to the announcement of the change in the share capital, and

T = subscription price/reduction price in relation to the change in the share capital

If the adjusted exercise price and/or the adjusted number of shares does not amount to whole numbers, each number shall be rounded down to the nearest whole number.

5.6 Changes in the nominal value of each individual share:

If it is decided to change the nominal value of the shares, warrants shall be adjusted as follows:

The exercise price for each non-exercised warrant shall be multiplied by the factor:

$$a = \frac{A}{B}$$

and the number of non-exercised warrants shall be multiplied by the factor:

$$\frac{1}{a}$$

where:

A = nominal value of each share after the change, and

B = nominal value of each share before the change

If the adjusted exercise price and/or the adjusted number of shares does not amount to whole numbers, each number shall be rounded down to the nearest whole number.

5.7 Payment of dividend:

If it is decided to pay dividends, the part of the dividends exceeding 10 per cent of the equity capital shall lead to adjustment of the exercise price according to the following formula:

$$E2 = E1 - \frac{U - U_{max}}{A}$$

where:

E2 = the adjusted exercise price

E1 = the original exercise price

U = dividends paid out

U_{max} = 10 per cent of the equity capital, and

A = total number of shares in Ascendis Pharma

If the adjusted exercise price does not amount to a whole number, it shall be rounded down to the nearest whole number.

The equity capital that shall form the basis of the adjustment above is the equity capital stipulated in the Annual Report to be adopted at the General Meeting where dividends shall be approved before allocation hereof has been made in the Annual Report.

5.8 Other changes in Ascendis Pharma's capital position:

In the event of other changes in Ascendis Pharma's capital position causing changes to the financial value of warrants, warrants shall (save as provided above) be adjusted in order to ensure that the changes do not influence the financial value of the warrants.

The calculation method to be applied to the adjustment shall be decided by an external advisor appointed by the Board of Directors.

It is emphasized that increase or reduction of Ascendis Pharma's share capital at market price does not lead to an adjustment of the subscription price or the number of shares to be subscribed.

5.9 Winding-up:

Should Ascendis Pharma be liquidated, the vesting time for all non-exercised warrants shall be changed so that the Warrantholder may exercise his/her warrants in an extraordinary exercise period immediately preceding the relevant transaction.

5.10 Merger and split:

If Ascendis Pharma merges as the continuing company, warrants shall remain unaffected unless, in connection with the merger, the capital is increased at a price other than the market price and in that case warrants shall be adjusted in accordance with clause 5.5.

If Ascendis Pharma merges as the terminating company or is split, the continuing company may choose one of the following possibilities:

- The Warrantholder may exercise all non-exercised warrants (inclusive of warrants not yet vested) immediately before the merger/split, or
- New share instruments in the continuing company/companies of a corresponding financial pre-tax value shall replace the warrants. On split the continuing companies may decide in which company/companies the Warrantholders shall receive the new share instruments.

5.11 Sale and exchange of shares:

If more than 50 per cent of the share capital in Ascendis Pharma is sold or is part of a share swap, Ascendis Pharma may choose one of the following possibilities:

- The Warrantholder may exercise all non-exercised warrants that are not declared null and void (inclusive of warrants not yet vested) immediately before the sale/swap of shares. Furthermore, the Warrantholder shall undertake an obligation to sell the subscribed shares on the same conditions as the other shareholders (when selling).
- Share instruments in the acquiring company of a corresponding pre-tax value shall replace the issued warrants.

5.12 Common provisions regarding 5.9-5.11:

If one of the transactions mentioned above is made, Ascendis Pharma shall inform the Warrantholder hereof by written notice. Upon receipt of the written notice, the Warrantholder shall have 2 weeks – in cases where the Warrantholder may extraordinarily exercise warrants, see 5.9-5.11 – to inform Ascendis Pharma in writing whether he/she will make use of the offer. If the Warrantholder has not answered Ascendis Pharma in writing within the limit of 2 weeks or fails to pay within the fixed time, warrants shall become null and void without further notice or compensation.

The Warrantholder's rights in connection with decisions made by any competent company body, see 5.9-5.11, shall be contingent on subsequent registration of the relevant decision with the Danish Commerce and Companies Agency provided that registration is a condition of its validity.

6. Stock Exchange listing

- 6.1** In the event that Ascendis Pharma's shares are listed on the stock exchange, the Warrantholder shall accept such changes to the warrants that are necessary for Ascendis Pharma's, the shareholders' and the Warranholders' fulfilment of their obligations, especially the duties of disclosure, to the stock exchange. Additionally the Warranholders shall be obligated to accept such lock-up periods regarding exercise of warrants or a sale of shares which is recommended to Ascendis Pharma by the investmentbanks. Finally the Warranholders shall be obligated to accept changes to the exercise periods, cf. in this respect above.

7. Transfer, pledge and enforcement

7.1 Issued warrants shall not be subject to charging orders, transfer of any kind, including in connection with division of property on divorce or legal separation, for ownership or as security without the consent of the Board of Directors. The Warrantholder's warrants may, however, be transferred to the Warrantholder's spouse/cohabitant and/or issue in the event of the Warrantholder's death. It is a condition precedent that the recipient signs the at any time applicable shareholders' agreement.

8. Subscription for new shares by exercise of warrants

8.1 Subscription for new shares by exercise of issued warrants must be made through submission by the Warrantholder no later than the last day of the relevant exercise period at 16:00 to Ascendis Pharma of an exercise notice drafted by Ascendis Pharma. The exercise notice shall be filled in with all information. The company must have received the exercise price for the new shares, payable as a cash contribution, by the last day of the relevant exercise period.

8.2 If the limitation period set forth in clause 8.1 expires as a result of Ascendis Pharma not having received the filled-in exercise notice or the payment by 16:00 of the last day of the exercise period, the subscription shall be deemed invalid, and in this situation the Warrantholder shall not be considered as having exercised his/her warrants for a possible subsequent exercise period.

8.3 Warrants not exercised by the Warrantholder during the last exercise period, i.e. where exercise notice and/or payment has not been effected by 21 August 2015, shall become null and void without notice or compensation.

8.4 When the capital increase caused by exercise of warrants has been registered with the Danish Commerce and Companies Agency, the Warrantholder shall receive proof of his shareholding in Ascendis Pharma.

9. The rights of new ordinary A-shares

9.1 New shares subscribed for by exercise of issued warrants shall in every respect have the same rights as the present A-shares in Ascendis Pharma in accordance with the Articles of Association for Ascendis Pharma in force from time to time.

For the time being, the following shall apply:

- That Ascendis Pharma's shareholders shall hold no pre-emptive rights to subscribe for warrants;
- That Ascendis Pharma's shareholders shall hold no pre-emptive rights to subscribe for new shares issued on the basis of warrants;
- That the face value of each share shall be DKK 1 or multiples hereof;
- That the shares shall be non-negotiable instruments issued in the name of the holder and the holders' names shall be entered into the Ascendis Pharma's register of owners;
- That new A-shares issued as a result of exercise of warrants shall carry the right to dividend and other rights in Ascendis Pharma from the time of registration of the capital increase with the Danish Commerce and Companies Agency; however, the B-shares and C-shares have certain preference rights.

9.2 Ascendis Pharma shall pay all costs connected with granting of warrants and later exercise thereof. Ascendis Pharma's costs in connection with issue of warrants and the related capital increase are estimated to DKK 50,000.

10. Sale of shares

10.1 When the Warrantholders have been registered as shareholders in Ascendis Pharma, the Warrantholders' shares may be sold in accordance with the provisions of the Shareholders' Agreement established between the Warrantholders and Ascendis Pharma's other shareholders.

11. Other provisions

11.1 The value attached to the subscription right shall not be included in the Warrantholder's salary, and any agreement made between the Warrantholder and Ascendis Pharma regarding pension or the like shall therefore not include the value of the Warrantholder's warrants.

11.2 If a relevant authority should establish that the issuance and/or exercise of warrants shall be considered a salary allowance with the consequence that Ascendis

Pharma shall pay holiday allowance or the like to the Warrantholder on the basis of the value of warrants, the subscription price shall be increased in order to compensate Ascendis Pharma for the amounts that have been paid to the Warrantholder in the form of holiday allowance or the like.

11.3 The fact that Ascendis Pharma offers warrants to Warrantholders shall not in any way obligate Ascendis Pharma to maintain the employment.

12. Tax implications

12.1 The tax implications connected to the Warrantholder's subscription for or exercise of warrants shall be of no concern to Ascendis Pharma.

13. Governing Law and Venue

13.1 Acceptance of warrants, the terms and conditions thereto and the exercise, and terms and conditions for future subscription for shares in Ascendis Pharma shall be governed by Danish law.

13.2 Any disagreement between the Warrantholder and Ascendis Pharma in relation to the understanding or implementation of the warrant scheme shall be settled amicably by negotiation between the parties.

13.3 If the parties fail to reach consensus, any disputes shall be settled in accordance with "Rules for hearing of cases in the Copenhagen Arbitration". The Copenhagen Arbitration shall appoint one arbitrator who shall settle the dispute according to Danish law.

13.4 In the event of discrepancies between the English and the Danish text the Danish text shall prevail.

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Appendix 2 to the Articles of Association of Ascendis Pharma A/S

Pursuant to authorisation in the articles of association for Ascendis Pharma A/S, the Board of Directors has resolved that the following terms and conditions shall apply to warrants which are granted to employees, consultants, advisors and board members according to the authorisation:

1. General

- 1.1 Ascendis Pharma A/S (hereinafter “Ascendis Pharma”) has decided to introduce an incentive scheme for employees, consultants, advisors and board members in Ascendis Pharma and its subsidiaries (hereinafter collectively referred to as “Warranholders”). The scheme is based on issuance of options, also called warrants (hereinafter only referred to as “warrants”), which are not subject to payment. Where below in clause 3.4 - 3.7 and clause 4.5 - 4.6 terms for vesting etc. are described as being dependant upon employment/affiliation with Ascendis Pharma, this shall be understood as a reference to the relevant subsidiary by which the Warranholders is employed/affiliated.
- 1.2 A warrant is a right, but not an obligation, during fixed periods (exercise periods) to subscribe for new ordinary A-shares in Ascendis Pharma at a price fixed in advance (the exercise price). The exercise price, which shall correspond to the market price at the date of issuance, shall be determined by the board of directors. Each warrant carries the right to subscribe for nominal DKK 1 ordinary A-share in Ascendis Pharma at the subscription price determined by the board of directors at the date of issuance.
- 1.3 Warrants will be offered to employees, consultants, advisors and board members in Ascendis Pharma and in its subsidiaries at the discretion of the Board of Directors after suggestion from the management of Ascendis Pharma A/S. The number of warrants offered to each individual shall be based on an individual evaluation of the Warranholder’s duties. It shall appear from the individual Warranholder’s warrant certificate how many warrants have been granted to the Warranholder and what the exercise price for the warrant is.

2. Granting/subscription of warrants

- 2.1 Warrantheolders who wish to subscribe the offered warrants shall sign a Warrant Certificate with this Appendix21 attached and, to the extent required by the Board of Directors, a Shareholders Agreement regulating the relationship between the Warrantheolders and Ascendis Pharma's other shareholders.
- 2.2 The granting of warrants shall not be subject to payment from the Warrantheolders.
- 2.3 Ascendis Pharma shall keep records of granted warrants and update the records at suitable intervals.

3. Vesting

- 3.1 The warrants shall be vested with 1/48 per month from the date of grant of the warrants covered by this Appendix 2. The board may have determined a different vesting period in its decision to issue warrants.
- 3.2 If Ascendis Pharma before 1/1 2014 merges as the terminating company or is split, cf. clause 5.10 or if more than 50 per cent of the share capital in Ascendis Pharma no later than 1/1 2014 is sold or is part of a share swap, cf. clause 5.11 (defined as an "Exit-event"), then 50% of the warrants not already vested on the time of the Exit-event shall vest at the time of the Exit-event.
- If the Exit-event occurs on or after 1/1 2014, then all warrants not vested at the time of the Exit-event shall be deemed 100% for vested at the time of the Exit-event.
- 3.3 If the stipulated fraction does not amount to a whole number of warrants, the number shall be rounded down to the nearest whole number.
- 3.4 Warrants shall only be vested to the extent the Warrantheolder is employed by Ascendis Pharma, cf. however clause 3.5 to 3.7 below.
- 3.5 In the event that the Warrantheolder terminates the employment contract and the termination is not a result of breach of the employment terms by Ascendis Pharma, and in the event that Ascendis Pharma terminates the employment

contract and the Warrantholder has given Ascendis Pharma good reason to do so, then the vesting of warrants shall cease from the time the employment is terminated, meaning from the first day when the Warrantholder is no longer entitled to salary from Ascendis Pharma, notwithstanding that the Warrantholder has actually ceased to perform his/her duties at an earlier date. In addition hereto the Warrantholder's right, if any, to receive warrants granted after termination of the employment shall cease.

- 3.6 In the event that the Warrantholder terminates the employment contract and the termination is a result of breach of the employment terms by Ascendis Pharma, or in the event that Ascendis Pharma terminates the employment contract and the Warrantholder having not given Ascendis Pharma good reason to do so, then warrants shall continue to vest as if the Warrantholder was still employed by Ascendis Pharma.
- 3.7 Should the Warrantholder materially breach the terms of the employment, the vesting of warrants shall cease from the date when the Warrantholder is dismissed due to the material breach.
- 3.8 Warrants issued to consultants, advisors and board members only vest to the extent that the consultant, advisor or board member acts on behalf of Ascendis Pharma as a consultant, advisor or board member.
- 3.9 If the Warrantholder takes leave – other than maternity leave – and the leave exceeds 60 days, the dates when the warrants shall be vested shall be postponed by a period corresponding to the duration of the leave.

4. Exercise

- 4.1 When a warrant has been vested, it may be exercised during the exercise periods. From 2013, there is two exercise periods of 2 times 3 weeks each year commencing on 1 January respectively 1 August and ending on 21 January respectively 21 August as follows:

1 – 21 January or 1 – 21 August 2013

1 – 21 January or 1 – 21 August 2014

1 – 21 January or 1 – 21 August 2015

1 – 21 January or 1 – 21 August 2016

1 – 21 January or 1 – 21 August 2017

1 – 21 January or 1 – 21 August 2018
1 – 21 January or 1 – 21 August 2019
1 – 21 January or 1 – 21 August 2020
1 – 21 January or 1 – 21 August 2021
1 – 21 January or 1 – 21 August 2022
1 – 21 January or 1 – 21 August 2023

- 4.2 If the last day of an exercise period is Saturday or Sunday, the exercise period shall also include the first weekday following the stipulated period.
- 4.3 When warrants have been vested, the Warrantholder shall be free to choose, which exercise period to apply for the vested warrants, cf. however, clause 4.5 below regarding material breach. It is, however, a condition for exercise that the Warrantholder in a given exercise period exercises warrants, which give a right to subscribe minimum nominal DKK 100 shares.
- 4.4 Warrants not exercised by the Warrantholder during the last exercise period, 1 – 21 August 2023, shall become null and void without further notice or compensation or payment of any kind to the Warrantholder.
- 4.5 The Warrantholder's exercise of warrants is in principle conditional upon the Warrantholder being employed in Ascendis Pharma at the time when warrants are exercised. In case of termination of the employment the following shall apply:
- a. In the event that Ascendis Pharma terminates the employment contract and the Warrantholder having given Ascendis Pharma good reason to do so, the Warrantholder is only entitled to exercise the warrants vested at the time of termination. Exercise shall take place during the first coming exercise period after termination of the employment, however the Warrantholder shall always have minimum 3 months from the date of termination to decide if warrants shall be exercised. To the extent that the first coming exercise period commences within 3 months from the date of actual termination the Warrantholder shall be entitled to exercise the warrants in the exercise period following the first coming exercise period. All vested warrants not exercised by the Warrantholder according to this clause shall become null and void without further notice or compensation or payment of any kind.
 - b. In the event that the Warrantholder terminate the employment, or in the event that Ascendis Pharma terminates the employment contract and the

Warrantholder have not given Ascendis Pharma good reason to do so, the Warrantholder is entitled to exercise the warrants as if the Warrantholder were still employed with Ascendis Pharma. Exercise shall take place in accordance with the general terms and conditions regarding exercise of warrants stipulated in clause 4.1 – 4.5. This provision shall apply if the employment contract is terminated due to retirement.

- c. If the employment is terminated as a consequence of summary dismissal of the Warrantholder on grounds of material breach, all warrants not exercised at that time shall become null and void without notice or compensation. If the material breach is committed prior to the dismissal the vesting and the right to exercise warrants shall be deemed to have ceased at the time of the material breach. The Warrantholder shall in this case, after demand from Ascendis Pharma, be obligated to sell to Ascendis Pharma shares which have been subscribed through exercise of warrants, after the date of the material breach. The shares shall be sold at a price corresponding to the subscription price paid by the Warrantholder.
- d. If the employment is terminated due to the death of the Warrantholder all warrants not exercised by the Warrantholder shall become null and void. However, the Ascendis Pharma Board of Directors may grant an exemption from this provision to enable the estate of the Warrantholder to exercise the issued warrants whether they have been vested at the time of the death or not on the condition that exercise be effected during the first exercise period commencing after the death.

4.6 If the Warrantholder is a consultant, advisor or board member the exercise of warrants is in principle conditional upon the Warrantholder being connected to Ascendis Pharma in this capacity at the time when warrants are exercised. In case that the consultant's, advisor's or board member's relationship with Ascendis Pharma should cease without this being attributable to the Warrantholder's actions or omissions the Warrantholder shall be entitled to exercise vested warrants in the exercise periods set forth in clause 4.1 above.

4.7 Ascendis Pharma's board of directors is in the event of a listing of the company's shares on a stock exchange entitled at its discretion to change the exercise periods in order to coordinate these with applicable rules for insider trading. Unless the Board of Directors resolves otherwise the exercise periods shall in the event of a listing be changed to two 21 day periods after respectively the annual report notification and the interim report (six months).

5. Adjustment of warrants

- 5.1** Changes in Ascendis Pharma’s capital structure causing a change of the potential possibility of gain attached to a warrant shall require an adjustment of the warrants.
- 5.2** Adjustments shall be made so that the potential possibility of gain attached to a warrant, in so far as possible, shall remain the same before and after the occurrence of an incident causing the adjustment. The adjustment shall be carried out with the assistance of Ascendis Pharma’s external advisor. The adjustment may be effected either by increase or reduction of the number of shares that can be issued following exercise of a warrant and/or an increase or reduction of the exercise price.
- 5.3** Warrants shall not be adjusted as a result of Ascendis Pharma’s issue of employee shares, share options and/or warrants as part of employee share option schemes (including options to Directors, advisors and consultants) as well as future exercise of such options and/or warrants. Warrants shall, furthermore, not be adjusted as a result of capital increases following the Warrantholders’ and others’ exercise of warrants in Ascendis Pharma.

5.4 Bonus shares

If it is decided to issue bonus shares in Ascendis Pharma, warrants shall be adjusted as follows:

The exercise price for each warrant not yet exercised shall be multiplied by the factor:

$$a = \frac{A}{(A + B)}$$

and the number of warrants not yet exercised shall be multiplied by the factor:

$$\frac{1}{a}$$

where:

A = the nominal share capital before issue of bonus shares, and

B = the total nominal value of bonus shares.

If the adjusted exercise price and/or the adjusted number of shares does not amount to whole numbers, each number shall be rounded down to the nearest whole number.

5.5 Changes of capital at a price different from the market price:

If it is decided to increase or reduce the share capital in Ascendis Pharma at a price below the market price (in relation to capital decreases also above the market price), warrants shall be adjusted as follows:

The exercise price for each non-exercised warrant shall be multiplied by the factor:

$$a = \frac{(A \times K) + (B \times T)}{(A + B) \times K}$$

and the number of non-exercised warrants shall be multiplied by the factor:

$$\frac{1}{a}$$

where:

A = nominal share capital before the change in capital

B = nominal change in the share capital

K = market price / closing price of the share on the day prior to the announcement of the change in the share capital, and

T = subscription price/reduction price in relation to the change in the share capital

If the adjusted exercise price and/or the adjusted number of shares does not amount to whole numbers, each number shall be rounded down to the nearest whole number.

5.6 Changes in the nominal value of each individual share:

If it is decided to change the nominal value of the shares, warrants shall be adjusted as follows:

The exercise price for each non-exercised warrant shall be multiplied by the factor:

$$a = \frac{A}{B}$$

and the number of non-exercised warrants shall be multiplied by the factor:

$$\frac{1}{a}$$

where:

A = nominal value of each share after the change, and

B = nominal value of each share before the change

If the adjusted exercise price and/or the adjusted number of shares does not amount to whole numbers, each number shall be rounded down to the nearest whole number.

5.7 Payment of dividend:

If it is decided to pay dividends, the part of the dividends exceeding 10 per cent of the equity capital shall lead to adjustment of the exercise price according to the following formula:

$$E2 = E1 - \frac{U - U_{max}}{A}$$

where:

E2 = the adjusted exercise price

E1 = the original exercise price

U = dividends paid out

$U_{max} =$ 10 per cent of the equity capital, and
 $A =$ total number of shares in Ascendis Pharma

If the adjusted exercise price does not amount to a whole number, it shall be rounded down to the nearest whole number.

The equity capital that shall form the basis of the adjustment above is the equity capital stipulated in the Annual Report to be adopted at the General Meeting where dividends shall be approved before allocation hereof has been made in the Annual Report.

5.8 Other changes in Ascendis Pharma's capital position:

In the event of other changes in Ascendis Pharma's capital position causing changes to the financial value of warrants, warrants shall (save as provided above) be adjusted in order to ensure that the changes do not influence the financial value of the warrants.

The calculation method to be applied to the adjustment shall be decided by an external advisor appointed by the Board of Directors.

It is emphasized that increase or reduction of Ascendis Pharma's share capital at market price does not lead to an adjustment of the subscription price or the number of shares to be subscribed.

5.9 Winding-up:

Should Ascendis Pharma be liquidated, the vesting time for all non-exercised warrants shall be changed so that the Warrantholder may exercise his/her warrants in an extraordinary exercise period immediately preceding the relevant transaction.

5.10 Merger and split:

If Ascendis Pharma merges as the continuing company, warrants shall remain unaffected unless, in connection with the merger, the capital is increased at a price other than the market price and in that case warrants shall be adjusted in accordance with clause 5.5.

If Ascendis Pharma merges as the terminating company or is split, the continuing company may choose one of the following possibilities:

- The Warrantholder may exercise all non-exercised warrants (inclusive of warrants not yet vested) immediately before the merger/split, or
- New share instruments in the continuing company/companies of a corresponding financial pre-tax value shall replace the warrants. On split the continuing companies may decide in which company/companies the Warrantholders shall receive the new share instruments.

5.11 Sale and exchange of shares:

If more than 50 per cent of the share capital in Ascendis Pharma is sold or is part of a share swap, Ascendis Pharma may choose one of the following possibilities:

- The Warrantholder may exercise all non-exercised warrants that are not declared null and void (inclusive of warrants not yet vested) immediately before the sale/swap of shares. Furthermore, the Warrantholder shall undertake an obligation to sell the subscribed shares on the same conditions as the other shareholders (when selling).
- Share instruments in the acquiring company of a corresponding pre-tax value shall replace the issued warrants.

5.12 Common provisions regarding 5.9-5.11:

If one of the transactions mentioned above is made, Ascendis Pharma shall inform the Warrantholder hereof by written notice. Upon receipt of the written notice, the Warrantholder shall have 2 weeks – in cases where the Warrantholder may extraordinarily exercise warrants, see 5.9-5.11 – to inform Ascendis Pharma in writing whether he/she will make use of the offer. If the Warrantholder has not answered Ascendis Pharma in writing within the limit of 2 weeks or fails to pay within the fixed time, warrants shall become null and void without further notice or compensation.

The Warrantholder's rights in connection with decisions made by any competent company body, see clause 5.9-5.11, shall be contingent on subsequent registration of the relevant decision with the Danish Commerce and Companies Agency provided that registration is a condition of its validity.

6. Stock Exchange listing

- 6.1** In the event that Ascendis Pharma's shares are listed on the stock exchange, the Warrantholder shall accept such changes to the warrants that are necessary for Ascendis Pharma's, the shareholders' and the Warranholders' fulfilment of their obligations, especially the duties of disclosure, to the stock exchange. Additionally the Warranholders shall be obligated to accept such lock-up periods regarding exercise of warrants or a sale of shares which is recommended to Ascendis Pharma by the investmentbanks. By accept of such lock-up periods, the period regarding exercise of warrants in 4.1 and 4.4 shall be extended with the nuber of days the lock-up period covers; however, no less than 180 days. Finally the Warranholders shall be obligated to accept changes to the exercise periods, cf. in this respect above.

7. Transfer, pledge and enforcement

- 7.1** Issued warrants shall not be subject to charging orders, transfer of any kind, including in connection with division of property on divorce or legal separation, for ownership or as security without the consent of the Board of Directors. The Warrantholder's warrants may, however, be transferred to the Warrantholder's spouse/cohabitant and/or issue in the event of the Warrantholder's death. It is a condition precedent that the recipient signs the at any time applicable shareholders' agreement.

8. Subscription for new shares by exercise of warrants

- 8.1** Subscription for new shares by exercise of issued warrants must be made through submission by the Warrantholder no later than the last day of the relevant exercise period at 16:00 CET to Ascendis Pharma of an exercise notice drafted by Ascendis Pharma. The exercise notice shall be filled in with all information. The company must have received the exercise price for the new shares, payable as a cash contribution, by the last day of the relevant exercise period.
- 8.2** If the limitation period set forth in clause 8.1 expires as a result of Ascendis Pharma not having received the filled-in exercise notice or the payment by 16:00 of the last day of the exercise period, the subscription shall be deemed invalid, and in this situation the Warrantholder shall not be considered as having exercised his/her warrants for a possible subsequent exercise period.

- 8.3** Warrants not exercised by the Warrantholder during the last exercise period, i.e. where exercise notice and/or payment has not been effected by 21 August 2023, shall become null and void without notice or compensation.
- 8.4** When the capital increase caused by exercise of warrants has been registered with the Danish Commerce and Companies Agency, the Warrantholder shall receive proof of his shareholding in Ascendis Pharma.
- 9. The rights of new ordinary A-shares**
- 9.1** New shares subscribed for by exercise of issued warrants shall in every respect have the same rights as the present A-shares in Ascendis Pharma in accordance with the Articles of Association for Ascendis Pharma in force from time to time. For the time being, the following shall apply:
- That Ascendis Pharma's shareholders shall hold no pre-emptive rights to subscribe for warrants;
 - That Ascendis Pharma's shareholders shall hold no pre-emptive rights to subscribe for new shares issued on the basis of warrants;
 - That the face value of each share shall be DKK 1 or multiples hereof;
 - That the shares shall be non-negotiable instruments issued in the name of the holder and the holders' names shall be entered into the Ascendis Pharma's register of owners;
 - That new A-shares issued as a result of exercise of warrants shall carry the right to dividend and other rights in Ascendis Pharma from the time of registration of the capital increase with the Danish Commerce and Companies Agency; however, the B-shares and C-shares have certain preference rights.
- 9.2** Ascendis Pharma shall pay all costs connected with granting of warrants and later exercise thereof. Ascendis Pharma's costs in connection with issue of warrants and the related capital increase are estimated to DKK 50,000.

10. Sale of shares

10.1 When the Warranholders have been registered as shareholders in Ascendis Pharma, the Warranholders' shares may be sold in accordance with the provisions of the Shareholders' Agreement established between the Warranholders and Ascendis Pharma's other shareholders.

11. Other provisions

11.1 The value attached to the subscription right shall not be included in the Warranholder's salary, and any agreement made between the Warranholder and Ascendis Pharma regarding pension or the like shall therefore not include the value of the Warranholder's warrants.

11.2 If a relevant authority should establish that the issuance and/or exercise of warrants shall be considered a salary allowance with the consequence that Ascendis Pharma shall pay holiday allowance or the like to the Warranholder on the basis of the value of warrants, the subscription price shall be increased in order to compensate Ascendis Pharma for the amounts that have been paid to the Warranholder in the form of holiday allowance or the like.

11.3 The fact that Ascendis Pharma offers warrants to Warranholders shall not in any way obligate Ascendis Pharma to maintain the employment.

12. Tax implications

12.1 The tax implications connected to the Warranholder's subscription for or exercise of warrants shall be of no concern to Ascendis Pharma.

13. Governing Law and Venue

13.1 Acceptance of warrants, the terms and conditions thereto and the exercise, and terms and conditions for future subscription for shares in Ascendis Pharma shall be governed by Danish law.

13.2 Any disagreement between the Warranholder and Ascendis Pharma in relation to the understanding or implementation of the warrant scheme shall be settled amicably by negotiation between the parties.

13.3 If the parties fail to reach consensus, any disputes shall be settled in accordance

with “Rules for hearing of cases in the Copenhagen Arbitration”. The Copenhagen Arbitration shall appoint one arbitrator who shall settle the dispute according to Danish law.

13.4 In the event of discrepancies between the English and the Danish text the Danish text shall prevail.

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***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

CONFIDENTIAL – EXECUTION VERSION

Exclusive Licence Agreement

between

Ascendis Pharma Ophthalmology Division A/S

as the Licensor or Ascendis on the one hand

and

Genentech, Inc.

and

F. Hoffmann-La Roche Ltd

together as the Licensee on the other hand

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THIS EXCLUSIVE LICENCE AGREEMENT is dated 31 July 2013 and made

BETWEEN:

- (1) **ASCENDIS PHARMA OPHTHALMOLOGY DIVISION A/S**, (“Licensor” or “Ascendis”), a company registered in Denmark with its registered office at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark;
- (2) **GENENTECH, INC.**, (“Genentech”), a Delaware corporation with its principal place of business at 1 DNA Way, South San Francisco, CA 94080, USA; and
- (3) **F. HOFFMANN-LA ROCHE LTD**, (“Roche”), a company registered in Switzerland with its registered office at Grenzacherstrasse 124, 4070 Basel, Switzerland.
(Genentech and Roche, together the “Licensee”)

Ascendis and the Licensee are each a “Party”, and together the “Parties”, to this Agreement.

Background:

- (A) Ascendis and its Affiliates Control proprietary rights, titles and interests in patents and technical information relating to the Ascendis Technology (such terms defined below).
- (B) The Licensee wishes to develop and to commercialise therapeutic and/or prophylactic compounds in combination with the Ascendis Technology in the Field and/or Diabetic Retinopathy (such terms defined below), and Ascendis wishes to grant the Licensee an exclusive worldwide licence under certain patents, technical information and other intellectual property in the Field and a non-exclusive worldwide licence under certain patents, technical information and other intellectual property in Diabetic Retinopathy, on the terms and conditions of this Agreement.

THE PARTIES AGREE THAT:

1. **Interpretation**

1.1 **Definitions**

“Accounting Standard” means, with respect to the Licensee, either: (a) International Financial Reporting Standards (“IFRS”); or (b) United States generally accepted accounting principles (“GAAP”), in either case, which standards or principles (as applicable) are currently used at the applicable time, and as consistently applied, by the Licensee.

“Affiliate” means any business Entity which from time-to-time controls, is controlled by or is under common control with a Party to this Agreement, in each case only for so long as such control exists. As used in this definition and the definitions of “Ascendis Entity” and “Change of Control” only, “control” of an Entity means the beneficial ownership (either directly or indirectly) of more than fifty per cent (50%) of the total voting power of the shares or securities then outstanding normally entitled to vote in elections of the board of directors or other managing authority of such Entity. With respect to the Licensee only, the term “Affiliate” shall not include Chugai Pharmaceutical Co. Ltd., 1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324, Japan (“Chugai”), unless the Licensee opts for such inclusion of Chugai by giving written notice to Ascendis.

“Applicable Laws” means all laws, statutes, codes, ordinances, rules and regulations that have been enacted by a Regulatory Authority in any jurisdiction in the Territory and which are in force as of the Effective Date or come into force during the term of this Agreement and that are applicable to the Licensed Products or the activities of the Parties under this Agreement, including, without limitation: (a) applicable regulations and guidelines of the FDA and other Regulatory Authorities and the ICH guidelines; (b) applicable Good Clinical Practices, Good Laboratory Practices and Good Manufacturing Practices promulgated by the FDA and other Regulatory Authorities or the ICH; and (c) all applicable industry and trade standards, including the applicable standards of the ISO with, at a minimum, the ISO 9001/9002 quality standards.

“Ascendis Entity” means Ascendis, the business or operating unit(s) of Ascendis or any business Entity which from time-to-time controls (as the term “controls” is defined in the definition of “Affiliate”) Ascendis, that is performing all or substantially all of Ascendis’ obligations under this Agreement.

“Ascendis FTE Costs” means, for all activities performed by Ascendis or its Affiliates in accordance with a Research and Technical Development Plan or as otherwise directed in writing by the Licensee, the product of: (a) the number of FTEs used by Ascendis or its Affiliates for such activities as set forth in a Research and Technical Development Plan or other written document approved by the Licensee; and (b) the Ascendis FTE Rate. For the avoidance of doubt, the activity of approved service providers will be charged as out-of-pocket costs, not as part of the Ascendis FTE Costs.

“Ascendis FTE Rate” means [***] per FTE, which amount is fully burdened and includes without limitation, for each FTE, [***].

“Ascendis Improvement” means: (a) any Improvement conceived or generated by either Party solely relating to the Ascendis Technology; or (b) any Improvement conceived or generated solely by employees, agents or service providers of Ascendis or its Affiliates which is not a Licensee Improvement. By way of clarification, the term “Ascendis Improvement” excludes Licensed Product Patents, Process Inventions and Joint Improvements.

“Ascendis Indemnitee” has the meaning ascribed to it in Clause 15.1.

“Ascendis Patents” means: (a) the patents and patent applications listed in Part 2 of Schedule 1 as of the Effective Date and any conversion, continuation, continuation-in-part, division, provisional or substitution thereof, and any patents issuing thereon, any reissues, re-examinations, confirmations or extensions of such patents (including supplementary protection certificates) and any foreign counterparts of such patent applications and patents in any country in the Territory; and (b) any and all other Patents that are Controlled by Ascendis or its Affiliates as of the Effective Date or at any time thereafter during the term of this Agreement that are necessary or useful to make, have made, use, sell, offer for sale or import a Licensed Product. By way of clarification, “Ascendis Patents” excludes Licensed Product Patents.

“Ascendis Research and Technical Development Plan Activities” means the Research and Technical Development Plan Activities allocated to Ascendis as set forth in a Research and Technical Development Plan.

“Ascendis Research and Technical Development Plan Expenses” means the following costs and expenses actually incurred by Ascendis after the Effective Date in carrying out the Ascendis Research and Technical Development Plan Activities:

- (A) the cost of activities performed by approved service providers (including without limitation Third Party manufacturing organisations) in accordance with the applicable Research and Technical Development Plan;

- (B) Ascendis FTE Costs; and
- (C) any other costs or expenses specifically identified and included in the applicable Research and Technical Development Plan, which, for the avoidance of doubt, may include, without limitation, pre-paid amounts.

“Ascendis Technical Information” means: (a) the Technical Information listed in Schedule 2 as of the Effective Date; and (b) any and all other Technical Information that is Controlled by Ascendis or its Affiliates, as of the Effective Date or at any time thereafter during the term of this Agreement, that is necessary or useful to make, have made, use, sell, offer for sale or import a Licensed Product.

“Ascendis Technology” means, as of the Effective Date or at any time thereafter during the term of this Agreement, Ascendis’ proprietary chemistry, materials and methodologies for [***], thereby allowing [***] in a controlled manner over time for a therapeutic or prophylactic effect.

“Bankrupt Party” has the meaning ascribed to it in Clause 18.3(A).

“Business Day” means a day (other than a Saturday or Sunday) on which banks are open for ordinary face to face banking business in Copenhagen (Denmark), Basel (Switzerland) and San Francisco (California, USA).

“Change of Control” means the occurrence of any of the following events: (a) any Competitor takes control (as the term “control” is defined in the definition of “Affiliate”) of an Ascendis Entity; or (b) an Ascendis Entity: (i) consolidates with, or merges with or into, a Competitor; or (ii) sells, assigns, conveys, transfers, leases or otherwise disposes of all or substantially all of its assets to any Competitor.

“Chugai” has the meaning ascribed to it in the definition of “Affiliate”.

“Class” means, as applicable, a Small Molecule, a Polypeptide or a Large Molecule.

“CMC Services” has the meaning ascribed to it in Clause 5.2.

“Competitor” means a Third Party that is a pharmaceutical or biotechnology company participating in the research, development and/or commercialisation of [***] as of the date of a Change of Control.

“Compulsory Sub-Licence” means a sub-licence granted to a Third Party, through the order, decree or grant of a governmental authority having competent jurisdiction, authorising such Third Party to manufacture, use, sale, offer for sale, import or export a Licensed Product in any country in the Territory with a royalty rate lower than the royalty rate provided by Clause 7.5, as may be reduced in accordance with Clauses 7.6 and/or 7.7.

“Confidential Information” means confidential Technical Information (of whatever kind and in whatever form or medium, including copies thereof): (a) disclosed by or on behalf of a Party in connection with this Agreement, whether prior to or during the term of this Agreement and whether disclosed orally, electronically, by observation or in writing; and/or (b) created by, or on behalf of, either Party, or created jointly by the Parties, in the course of this Agreement. “Confidential Information” includes confidential Technical Information regarding such Party’s research, development plans, clinical trial designs, preclinical and clinical data, technology, products, business information or objectives and other information of the type that is customarily considered to be confidential information by Parties engaged in activities that are substantially similar to the activities being engaged in by the Parties pursuant to this Agreement. The following shall be deemed the Confidential Information of the Licensee: any and all financial or product pipeline information related to the Licensee provided to Ascendis (whether provided by the Licensee itself or through a Third Party), as well as Licensee Technology, Licensee Improvements, Process Inventions, Licensed Product Patents and the Research and Technical Development Plans. The following shall be deemed the Confidential Information of Ascendis: Ascendis Technology, Ascendis Technical Information, Ascendis Improvements, Ascendis Patents and Licensed Product Patents. The following shall be deemed the Confidential Information of both Parties: the terms and conditions of this Agreement.

“Confidentiality Agreement” means the mutual confidentiality agreement between Ascendis and Genentech, dated [***], as amended and replaced by the non-disclosure agreement between Ascendis and Genentech, dated [***].

“Control” or “Controlled” means, with respect to an item of information or Intellectual Property, that a Party has the right, power and legal authority, whether arising by ownership, licence or other authorisation, to disclose, and/or to grant and authorise licences or sub-licences under, such items as required under the terms of this Agreement, without violating the terms of any written agreement with any Third Party under which such Party or its Affiliates first acquired such rights to such item of information or Intellectual Property.

“Diabetes” has the meaning ascribed to it in Schedule 3. By way of clarification and notwithstanding anything to the contrary, for the purpose of this Agreement, the term “Diabetes” excludes Diabetic Retinopathy.

“Diabetic Retinopathy” means [***].

“Diligent Efforts” means with respect to a Party the level of efforts and resources such Party would typically exert in similar circumstances pursuing the development and commercialisation of a similar product with similar market potential taking into account the stage of development or commercialisation, market potential and market size, the product life cycle, the risk of development or commercialisation of the Licensed Product, the cost effectiveness of efforts or resources, the competitiveness of alternative products that are or are expected to be in the marketplace, the scope and duration of patent rights or other proprietary rights related to the Licensed Product, and the profitability of the Licensed Product and alternative products. The efforts and resources of each Party’s respective Affiliates and Sub-Licensees shall count towards that Party’s own Diligent Efforts. Notwithstanding the foregoing, the exercise of diligence by the Licensee shall be determined by judging the Licensee’s commercially reasonable efforts taken as a whole, because the Licensee does not always seek to market its own products in every country or seek to obtain Regulatory Approval in every country or for every potential indication.

“Effective Date” means the date of this Agreement.

“Entity” means, and includes, any person, firm or company or group of persons or unincorporated body.

“Excluded Indications” means the diseases, conditions or disorders listed in Schedule 3, excluding Diabetic Retinopathy.

“Executives” means the Vice President, Global Head of Ophthalmology at the Licensee and the Chief Executive Officer at Ascendis.

“FDA” means the US Food and Drug Administration or any successor agency with comparable responsibilities.

“Feasibility Study Agreement” means the feasibility study agreement between Ascendis and Roche, dated [***].

“Field” means the treatment and/or prevention of any disease, condition or disorder of the [***], excluding Diabetic Retinopathy and the Excluded Indications.

“First Commercial Sale” means the first invoiced sale of a Licensed Product to a Third Party following the receipt of any Regulatory Approval required for the sale of such Licensed Product in a country, or if no such Regulatory Approval is required, the date of the first invoiced sale of a Product to a Third Party in such country.

“Force Majeure” means any circumstances not within the reasonable control of the Party concerned including, without limitation: (a) any strike, lockout or other industrial action, or any shortage of or difficulty in obtaining labour, fuel, raw materials or components; (b) any destruction, temporary or permanent breakdown, malfunction or damage of or to any premises, plant, equipment (including computer systems) or materials; (c) any breach of contract, default or insolvency by or of any Third Party, other than an Affiliate of the Party affected by the force majeure, or an employee or officer of that Party or Affiliate; (d) any action taken by a governmental or public authority imposing an embargo, export or import restriction, rationing, quota or other restriction or prohibition; (e) any civil commotion or disorder, riot, invasion, war, threat of or preparation for war; or (f) any accident, fire, or explosion, (other than in each case, one caused by a breach of contract by or assistance of the Party concerned) storm, flood, earthquake, subsidence, epidemic or other natural physical disaster. Notwithstanding the foregoing, lack of funds, manpower or equipment, interruption or failure of utility service and the fault or misconduct by any personnel engaged by a Party shall not be an event of Force Majeure.

“FTE” means a full time equivalent person year of work (consisting of 1673 hours per year for work in Denmark or 1768 hours per year for work in Germany), prorated on a daily or hourly basis as necessary.

“Generic Product” means a product (other than a Licensed Product) that is [***] where such compound is: [***].

“Glp-1 Product” means [***].

“Glucagon Product” means [***].

“Good Clinical Practice” means the applicable principles and guidelines for good clinical practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation those set out in the Harmonised Tripartite Guideline for Good Clinical Practice as finalised by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

“Good Laboratory Practice” means the applicable principles and guidelines for good laboratory practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation those set out in the OECD Principles of Good Laboratory Practice published by the Organisation for Economic Co-Operation and Development.

“Good Manufacturing Practice” means all applicable principles and guidelines for good manufacturing practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time-to-time, including without limitation as specified in the applicable provisions of (i) European Directive 2003/94/EC and further guidance as published by the European Commission in Volume IV of “The rules governing medicinal products in the European Community” and (ii) Title 21 Parts 210 and 211 of the US Code of Federal Regulations (21 CFR, parts 210 and 211).

“ICH” means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

“Improvement” means any improvement, discovery, invention, development, enhancement, modification, technical information, whether or not patentable, made after the Effective Date.

“Indemnified Party” has the meaning ascribed to it in Clause 15.3.

“Insulin Product” means [***].

“Intellectual Property” means registered or unregistered trade marks, Patents, registered designs, unregistered design rights, business, company, domain or product names, service marks, copyright, know-how, Confidential Information, database rights, any rights in clinical study results, applications for and the right to apply for any of the foregoing, and any similar or analogous rights anywhere in the Territory.

“Intellectual Property Office” means the official local patent, trade mark or other Intellectual Property registry in each part of the Territory responsible for granting, maintaining records of, Patents, trade marks or other Intellectual Property and any instruments made in respect thereof.

“ISO” means the International Organization for Standardization.

“Joint Development Committee” or “JDC” means the joint development committee established under Clause 4.6.

“Joint Improvements” means any Improvements conceived or generated during the course of, and in connection with, this Agreement by employees, agents or service providers of both Ascendis and the Licensee or their respective Affiliates or Sub-Licensees, excluding Licensed Product Patents, Ascendis Improvements, Licensee Improvements and Process Inventions.

“Large Molecule” means a molecule that is not a Polypeptide or a Small Molecule.

“Licensed Product” means any combination of the Ascendis Technology with a therapeutic or prophylactic compound (including Small Molecules, Polypeptides or Large Molecules), regardless of its finished form, formulation or dosage, excluding Glucagon Product, Glp-1 Product and/or Insulin Product and any combination of Glucagon Product, Glp-1 Product and/or Insulin Product.

“Licensed Product Patent” means any and all Patents that are Controlled by Ascendis or the Licensee or their respective Affiliates claiming a Licensed Product, or its use or formulation. By way of clarification, the term “Licensed Product Patent” excludes Ascendis Patents, Licensee Technology, Licensee Improvements, Process Inventions and Joint Improvements.

“Licensee Commercialised Compound” means any Licensee Proprietary Compound which is, or is a part of, a product that is commercialised by the Licensee.

“Licensee Improvement” means: (a) any Improvement conceived or generated by either Party solely relating to the Licensee Technology; or (b) any Improvement conceived or generated solely by employees, agents or service providers of the Licensee or its Affiliates which is not an Ascendis Improvement. By way of clarification, the term “Licensee Improvement” excludes Ascendis Improvements, Licensed Product Patents, Process Inventions and Joint Improvements.

“Licensee Indemnitee” has the meaning ascribed to it in Clause 15.2.

“Licensee Proprietary Compound” means a therapeutic or prophylactic compound the manufacture, use, sale, offer for sale or importation of which would infringe a Valid Claim of a Patent that is Controlled by the Licensee.

“Licensee Technology” means the Licensee’s proprietary: (a) therapeutic or prophylactic compounds and their use; and (b) manufacturing methods.

“Loss” or “Losses” means any and all losses, liabilities, damages, fines, penalties, costs or expense (including reasonable attorneys’ fees and other expenses of litigation).

“Manufacture” or “Manufacturing” means any manufacturing activity of any Licensed Product, or any ingredient thereof, including manufacturing for pre-clinical or clinical use, or commercial sale, testing, handling, packaging and storage, ongoing stability tests and regulatory activities related to any of the foregoing.

“Marketing Authorisation” means the authorisation issued by the relevant Regulatory Authority necessary to place on the market Licensed Product in any country or regulatory jurisdiction, but for the avoidance of doubt shall not include pricing and reimbursement approvals or inclusion on the official list of reimbursable drugs.

“Net Sales” means the sum of:

- (A) in the case of sales of Licensed Product by the Licensee or its Affiliates, with respect to a given period of time, the amount calculated by subtracting from the Sales of such Licensed Product:
 - (1) a [***] deduction of [***];
 - (2) uncollectible amounts accrued during such period based on a proportional allocation of the total bad debts accrued during such period;
 - (3) credit card charges (including processing fees) accrued during such period on such Sales; and

- (4) government mandated fees and taxes and other government charges accrued during such period for such Licensed Product including, for example, any fees, taxes or other charges that become due in connection with any healthcare reform, change in government pricing or discounting schemes, or other action of a government or regulatory body,

provided that the foregoing deductions under (1) to (4) were not already taken as a gross-to-net deduction in accordance with the Accounting Standard in the calculation of Sales of such Licensed Product for such period; and

- (B) in the case of sale of Licensed Product by any Sub-Licensee that is not an Affiliate, the net sales amounts reported to the Licensee in accordance with the Sub-Licensee's contractual terms and its then currently used accounting standards.

For clarity, the following shall not be included in "Net Sales": (i) Licensed Products supplied as samples for use in non-clinical studies, transferred for administration to patients enrolled in clinical trials or distributed through a not-for-profit foundation at cost or no charge to eligible patients; (ii) Licensed Product used as samples at cost or no charge to promote additional Net Sales, in amounts consistent with normal business practices of the Licensee or its Affiliates or Sub-Licensees or in any tests or studies necessary to comply with any Applicable Laws or request by a Regulatory Authority or governmental authority; and (iii) any Sub-Licensee sales as reported to Licensee in accordance with Compulsory Sub-Licence agreements.

In the case of any sale of a Licensed Product between the Licensee and its Affiliates or Sub-Licensees for resale, Net Sales shall be calculated as above only on the first arm's length sale thereafter to a Third Party.

In the event a Licensed Product is sold in combination with one or more other active ingredients or other products that are not subject to this Agreement (as used in this definition of Net Sales, a "Combination"), then for each Quarterly Period and on a country-by-country basis, the gross amount invoiced for that Licensed Product shall be calculated [***]. In the event that the other active ingredient is not sold separately, then the gross amount invoiced for that Licensed Product, as applicable, shall be calculated [***]. In the event that a particular Combination is not addressed by the foregoing, Net Sales for purposes of this Agreement shall be determined by the Parties in good faith.

"Non-Bankrupt Party" has the meaning ascribed to it in Clause 18.3(A).

"Obesity" has the meaning ascribed to it in Schedule 3.

"Other Licensed Product" means a Licensed Product other than a Ranibizumab Licensed Product.

"Patents" means any and all: (a) issued patents, including inventor's certificates; (b) patent applications, including any conversion, continuation, continuation-in-part, division, provisional or substitution thereof, and any patents issuing thereon; (c) any reissues, re-examinations, confirmations or extensions of such patents (including supplementary protection certificates); and (d) any foreign counterparts of such patent applications and patents in any country in the Territory. By way of clarification, for the purpose of the definition of "Valid Claim" only, the term "Patents" excludes patent applications.

“Phase I Trial” means, with respect to a Licensed Product, any human clinical trial conducted in any country that generally provides for the first introduction into humans of a pharmaceutical product which provides a preliminary assessment of safety and tolerability of such pharmaceutical product in healthy volunteers or patient volunteers, or otherwise generally consistent with U.S. 21 C.F.R. §312.21(a) with respect to the United States (or corresponding laws with respect to other jurisdictions as applicable).

“Phase II Trial” means, with respect to a Licensed Product, any human clinical trial conducted in any country that is designed: (a) to evaluate the efficacy of the pharmaceutical product for a particular indication or indications in patient volunteers with the indication under study and to assess side effects; or (b) to support an additional Phase II Trial or any Phase III Trial.

“Phase III Trial” means, with respect to a Licensed Product, any human clinical trial conducted in any country after preliminary evidence suggesting acceptable efficacy and safety of the pharmaceutical product has been obtained in prior studies, which is intended to gather additional information to evaluate the overall safety and efficacy of the pharmaceutical product and provide an adequate basis for physician labelling.

“Post-Generic Launch Quarterly Period” has the meaning ascribed to it in Clause 7.6.

“Pre-Generic Launch Quarterly Period” has the meaning ascribed to it in Clause 7.6.

“Polypeptide” means a polypeptide [***].

“Process Inventions” means any and all Technical Information, Patents or other Intellectual Property generated by or on behalf of the Licensee relating to process optimisation, process development, up-scaling and/or manufacturing of Licensed Products. By way of clarification, the term “Process Inventions” excludes process optimisation, process development, up-scaling and/or manufacturing of Licensed Products if it is not related to the Ascendis Technology.

“Product and Release Services” has the meaning ascribed to it in Clause 5.2.

“Quarterly Period” means each period of three months commencing on 01 January, 01 April, 01 July and 01 October in a given calendar year.

“Ranibizumab” means: (a) the Licensee’s proprietary drug, ranibizumab, which is the active pharmaceutical ingredient in the product marketed as Lucentis® as of the Effective Date; and (b) [***].

“Ranibizumab Licensed Product” means a Licensed Product containing Ranibizumab.

“Regulatory Approval” means all necessary approvals (including Marketing Authorisations, pricing and reimbursement approvals and inclusion on the official list of reimbursable drugs, as applicable) for the sale of Licensed Product for one or more indications in a country or regulatory jurisdiction.

“Regulatory Authority” means any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in any jurisdiction in the Territory involved in the granting of Regulatory Approval for, or involved in the regulation of, pharmaceutical products.

“Research and Technical Development Plan” means a research and technical development plan detailing: (a) the activities to be performed by the Parties (themselves or through their Affiliates or Sub-Licensees) in connection with the research and technical development of a Licensed Product under this Agreement; and (b) the deliverables, timetable and budget with respect to the Research and Technical Development Plan Activities.

“Research and Technical Development Plan Activities” means the activities performed (or to be performed) by or on behalf of each Party under a Research and Technical Development Plan.

“Research Collaboration Agreement” means the research collaboration agreement between Ascendis Pharma A/S and Genentech, dated [***], as amended on [***] and as amended and restated on [***].

“Reservation Period” has the meaning ascribed to it in Clause 2.3(E)(3).

“Reserved Compound” has the meaning ascribed to it in Clause 2.3(E).

“Royalty Term” has the meaning ascribed to it in Clause 7.4.

“Sales” means, with respect to a Licensed Product in a particular period, the amount stated in the Licensee’s sales line of its externally published audited financial statements with respect to such Licensed Product for such period (excluding sales to any Sub-Licensee for the purpose of resale). This amount reflects the gross invoice price at which such Licensed Product was sold or otherwise disposed of to Third Parties (excluding sales to any Sub-Licensee for the purpose of resale) in such period reduced by gross-to-net deductions, if not previously deducted from such invoiced amount, taken in accordance with the Accounting Standards.

By way of example, the gross-to-net deductions taken in accordance with the Accounting Standard as of the Effective Date include the following:

- (A) credits, reserves or allowances granted for: (i) damaged, outdated, returned, rejected, withdrawn or recalled Licensed Product; (ii) wastage replacement and short-shipments; (iii) billing errors; and (iv) indigent patient and similar programs (e.g., price capitation);
- (B) governmental price reductions and government mandated rebates;
- (C) chargebacks, including those granted to wholesalers, buying groups and retailers;
- (D) customer rebates, including cash sales incentives for prompt payment, cash and volume discounts; and
- (E) taxes, duties and any other governmental charges or levies imposed upon or measured by the import, export, use, manufacture or sale of a Licensed Product (excluding income or franchise taxes).

For the purpose of clarity, sales by the Licensee and its Affiliates to any Sub-Licensee for the purpose of resale shall be excluded from the term “Sales”. Any Sub-Licensee sales as reported to the Licensee in accordance with any Compulsory Sub-Licence agreements shall be excluded from the Sales amount.

“Sanofi Agreement” means the licence agreement between Ascendis Pharma A/S and Sanofi-Aventis Deutschland GmbH, dated 15 December 2010.

“SDEA” has the meaning ascribed to it in Clause 9.1.

“Severe Material Breach” means a material breach that has a serious adverse effect on the benefit which the terminating Party would otherwise derive from any of the obligations set out in Clauses 2.1, 2.3, 2.5, 10, 11 and 14.

“Small Molecule” means a non-peptidic molecule with a molecular weight of less than [***], including, without limitation, an amino acid.

“Sub-Licensee” means any Entity that has been granted a sub-licence by either Party of its rights granted hereunder in accordance with Clause 2.4.

“Target” means a molecule that a therapeutic or prophylactic compound in a Licensed Product directly binds to and modulates.

“Technical Information” means any and all: (a) identifiable know-how, data, inventions, discoveries, findings, methods, proprietary information, processes, techniques, materials and other information and technology (whether patentable or not) including formulae, biological materials, practices, test data (including pharmacological, toxicological and clinical information and related reports, statistical analyses, expert opinions and the like), analytical and quality control data, marketing, pricing, distribution, cost and sales data or descriptions; and (b) all Intellectual Property with respect to the items in subsection (a) above other than Patents. For clarity, as used in this Agreement, the term “Technical Information” excludes Patents.

“Territory” means worldwide.

“Third Party” means any Entity other than Ascendis or its Affiliates or its Sub-Licensees, or the Licensee or its Affiliates or its Sub-Licensees.

“Third Party Claim” means any action, suit or other proceedings brought by a Third Party.

“Third Party Licences” has the meaning ascribed to it in Clause 7.7.

“TransCon Hydrogel” means Ascendis’ proprietary [***] hydrogel containing TransCon Linkers, [***].

“TransCon Linker” means Ascendis’ proprietary linker used in [***].

“United States”, “US” or “USA” means the United States of America, its territories and possessions as of the Effective Date, including the Commonwealth of Puerto Rico.

“Valid Claim” means any claim of a Patent that has not expired or been disclaimed, abandoned or dedicated to the public, or held revoked, unenforceable, unpatentable or invalid (whether through reexamination, reissue, opposition or otherwise) by a decision of a court or governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time frame allowed for appeal.

“**VAT**” means value added tax as provided for in the Value Added Tax Act 1994 and legislation supplemental thereto, TVA or any other system of value added tax as provided for in Council Directive 2006/112/EC applied in any Member State of the European Union and any other similar turnover, sales or purchase, tax or duty levied by any other jurisdiction whether central, regional or local.

1.2 **Construction**

In this Agreement where the context admits:

- (A) references to any statute or statutory provisions shall be deemed to refer to those provisions as amended or re-enacted or as their application is modified by other provisions from time-to-time and any reference to a statutory provision shall include any subordinate legislation made from time-to-time under that provision;
- (B) references to “this Agreement” or to any other agreement or document referred to in this Agreement mean this Agreement or such other agreement or document as may be amended, varied, supplemented, modified or novated from time-to-time, and include the Schedules;
- (C) references to Clause(s) and Schedule(s) are references to clause(s) and schedule(s) of and to this Agreement, and each of the Schedules shall have effect as if set out in this Agreement;
- (D) references to “proprietary” mean Controlled by a Party, but do not infer any requirement of a Patent;
- (E) the headings and sub-headings in this Agreement are inserted for convenience only and shall not affect the construction of this Agreement;
- (F) the singular includes the plural and vice versa, and references to the masculine, feminine and the neuter shall include all such genders;
- (G) references to any Party include its successors and permitted assigns;
- (H) the symbol “€” means the lawful currency of the member states of the European Union that adopt the single currency in accordance with the EC Treaty, known as the “Euro”; and
- (I) the symbol “\$” means the lawful currency of the United States of America, known as the “US Dollar”.

2. **Grants and Restrictions**

2.1 Ascendis hereby grants to the Licensee and its Affiliates:

- (A) an exclusive (even as to Ascendis and subject to Clauses 4.4 and 18.1), royalty-bearing (in accordance with Clause 7) licence (with the right to grant sub-licences subject to Clause 2.4) under the Licensed Product Patents, Ascendis Patents, Ascendis Technical Information, Ascendis Improvements and Ascendis’ and its Affiliates’ interest in Joint Improvements, in each case that are Controlled by Ascendis or its Affiliates, to make, have made, use, sell, offer for sale or import Licensed Product in the Field in the Territory; and

- (B) a non-exclusive (subject to Clause 18.1), royalty-bearing (in accordance with Clause 7) licence (with the right to grant sub-licences subject to Clause 2.4) under the Licensed Product Patents, Ascendis Patents, Ascendis Technical Information, Ascendis Improvements and Ascendis' and its Affiliates' interest in Joint Improvements, in each case that are Controlled by Ascendis or its Affiliates, to make, have made, use, sell, offer for sale or import Licensed Product in Diabetic Retinopathy in the Territory.

2.2 The Licensee hereby grants to Ascendis and its Affiliates a non-exclusive, royalty-free, perpetual licence (with the right to grant sub-licences subject to Clause 2.4) under the Licensed Product Patents, Process Inventions and the Licensee's and its Affiliates' interest in Joint Improvements, in each case that are Controlled by the Licensee or its Affiliates, to make, have made, use, sell, offer for sale or import Licensed Product outside of the Field in the Territory.

2.3 Restrictions

- (A) Other than pursuant to this Agreement, neither Ascendis nor its Affiliates shall: (i) conduct, directly or indirectly, any research, development or commercialisation of any Ascendis Technology, Ascendis Technical Information, Ascendis Improvements and/or Ascendis' and its Affiliates' interest in Joint Improvements for use in the Field in the Territory; or (ii) sell, license, transfer or otherwise dispose of the Licensed Product Patents, Ascendis Patents, Ascendis Technical Information, Ascendis Improvements and/or Ascendis' and its Affiliates' interest in Joint Improvements to any Third Party for use with a Generic Product in the Field in the Territory.
- (B) Other than pursuant to this Agreement, neither Ascendis nor its Affiliates shall: (i) conduct, directly or indirectly, any commercialisation of any Ascendis Technology, Ascendis Technical Information, Ascendis Improvements and/or Ascendis' and its Affiliates' interest in Joint Improvements for use in Diabetic Retinopathy in the Territory, except in relation to products whose first Marketing Authorisation (irrespective of ownership) is for [***]; or (ii) sell, license, transfer or otherwise dispose of the Licensed Product Patents, Ascendis Patents, Ascendis Technical Information, Ascendis Improvements and/or Ascendis' and its Affiliates' interest in Joint Improvements to any Third Party for use with a Generic Product in Diabetic Retinopathy in the Territory, except in relation to products whose first Marketing Authorisation (irrespective of ownership) is for [***].
- (C) Other than pursuant to this Agreement, neither Ascendis nor its Affiliates shall conduct, directly or indirectly, any research or development of any Ascendis Technology, Ascendis Technical Information, Ascendis Improvements and/or Ascendis' and its Affiliates' interest in Joint Improvements for use in Diabetic Retinopathy in the Territory, except that nothing in this Clause 2.3(C) shall prevent Ascendis, its Affiliates or its licensee under the Sanofi Agreement from researching and developing products in Diabetic Retinopathy before having completed development in, or obtained Marketing Authorisation for, [***].
- (D) During the term of this Agreement, neither Ascendis nor its Affiliates shall develop or commercialise outside the Field or outside Diabetic Retinopathy, in each case in the Territory, any Licensed Product: (i) that is the subject of an active Research and Technical Development Plan and/or in active clinical development and/or subject to milestone or royalty obligations under this Agreement; and (ii) where the therapeutic or prophylactic compound in such Licensed Product is a Licensee Proprietary Compound.

- (E) The Licensee may notify Ascendis of up to: [***], and neither Ascendis nor its Affiliates shall initiate research, development or commercialisation activities with such Reserved Compounds as a Licensed Product outside the Field or outside Diabetic Retinopathy, in each case in the Territory, provided that:
- (1) such restriction shall not apply to Licensee Commercialised Compounds which Ascendis or its Affiliates can demonstrate are subject to an active research or development plan of Ascendis or its Affiliates at the time of such notification;
 - (2) if the Licensee notifies Ascendis of [***] Licensee Commercialised Compounds pursuant to Clause 2.3(E)(ii) above in such [***] period, then the Licensee shall notify Ascendis of [***] Reserved Compound to which such restriction shall no longer apply; and
 - (3) such restriction shall, in respect of each Reserved Compound, apply only until the earlier of: (i) [***] after the applicable notification date under Clause 2.3(E)(i) or 2.3(E)(ii) above; or (ii) [***], on a Reserved Compound-by-Reserved Compound basis (“Reservation Period”).

On expiry of the Reservation Period for a Reserved Compound, such Reserved Compound ceases to be a Reserved Compound and, subject to Clause 2.3(D), nothing in this Clause 2.3(E) shall prevent Ascendis or its Affiliates from developing or commercialising it in a Licensed Product outside the Field or outside Diabetic Retinopathy, in each case in the Territory.

- (F) On or after the Effective Date, neither Ascendis nor its Affiliates shall enter into any licence and/or provide any Ascendis Patents, Ascendis Technology, Ascendis Technical Information, Ascendis Improvements, Licensed Product Patents and/or Ascendis’ and its Affiliates’ interest in Joint Improvements for use in Diabetic Retinopathy in the Territory; provided that nothing in this Clause 2.3(F) shall prejudice or otherwise affect any rights or licences granted pursuant to the Sanofi Agreement for Diabetic Retinopathy prior to the Effective Date.
- (G) For the avoidance of doubt, Clauses 2.3(A) to 2.3(F) apply to Ascendis and its Affiliates only, and do not apply to: (i) Sub-Licensees or licensees of Ascendis or its Affiliates; or (ii) Third Parties. In addition, the Licensee shall have the sole right, but not the obligation, to enforce Clauses 2.3(A) to 2.3(F).
- (H) Neither the Licensee nor its Affiliates shall: (i) conduct, directly or indirectly, any research, development or commercialisation of any Ascendis Patents, Ascendis Technology, Ascendis Technical Information, Ascendis Improvements, Licensed Product Patents and/or Ascendis’ and its Affiliates’ interest in Joint Improvements for use outside the Field and outside Diabetic Retinopathy in the Territory; or (ii) sell, license, transfer or otherwise dispose of: (a) Licensed Product; or (b) any rights in the Licensed Product Patents, Ascendis Patents, Ascendis Technical Information, Ascendis Improvements to any Third Party, in each case for use outside the Field and outside Diabetic Retinopathy in the Territory. The restriction in this Clause 2.3(H) shall continue only for so long as such activities would infringe a Valid Claim in a Licensed Product Patent and/or Ascendis Patent.

- 2.4 Each Party agrees that:
- (A) any and all sub-licences granted under Clauses 2.1 and 2.2 shall be on terms consistent with the terms of this Agreement, contain obligations on each Sub-Licensee to perform and observe terms and conditions similar to those contained herein so far as the same are applicable;
 - (B) it shall be liable to the other Party for any acts and omissions of its Sub-Licensee that cause any breach of the provisions of this Agreement; and
 - (C) it shall, within thirty (30) days of the grant of each sub-licence, provide the other Party with a copy of such sub-licence, provided that [***].
- 2.5 Ascendis shall use its best efforts not to commit any acts or omissions that could cause a material breach of any licence agreement pursuant to which Ascendis has rights to Intellectual Property that it has sub-licensed to the Licensee under this Agreement, such that its Third Party licensor terminates or amends such licence agreement in any way that materially adversely affects a licence or other right granted to the Licensee under this Agreement that is used in a Licensed Product being developed (including under an active Research and Technical Development Plan) or commercialised by the Licensee. Ascendis shall not exercise any rights it may have with respect to any such licence agreement, or amend, terminate, or waive any of its rights under, such licence agreement in any way that materially adversely affects a licence or other right granted to the Licensee under this Agreement that is used in a Licensed Product being developed (including under an active Research and Technical Development Plan) or commercialised by the Licensee.
- 2.6 Only the licences granted or retained pursuant to the express terms of this Agreement shall be of any legal force or effect. No other licence rights shall be created by implication, estoppel or otherwise under this Agreement.
- 2.7 Each Party shall procure that its Affiliates shall comply with the terms and conditions of this Agreement and shall be liable to the other Party for any acts or omissions of such Affiliates which are not in compliance with the terms and conditions of this Agreement.

3. **Technical Information and Patents**

- 3.1 Within [***] of the Effective Date, Ascendis shall deliver and provide to the Licensee the items of Ascendis Technical Information listed in Schedule 2.
- 3.2 Ascendis shall use its Diligent Efforts to provide the Licensee with any additional Technical Information that is not specified in Schedule 2 but is Controlled by Ascendis and/or its Affiliates relating to the Ascendis Technical Information or Ascendis Technology during the term of this Agreement that is necessary or useful for the Licensee to make, have made, use, sell, offer for sale or import Licensed Product in the Field or Diabetic Retinopathy in the Territory. Ascendis' fees for the provision of such additional Technical Information, upon the Licensee's request, shall be charged at the Ascendis FTE Rate.

3.3 Upon the Licensee's written request, but in no event more than once per calendar year during the term of this Agreement, Ascendis shall provide [***] to the Licensee an updated (as of the date the request is received by Ascendis) of Part 2 of Schedule 1 and/or Schedule 2.

4. **Development and Commercialisation**

4.1 The Parties shall perform and complete, or cause the performance and completion of, their respective Research and Technical Development Plan Activities, and deliver to each other a summary of the results (including raw data if reasonably requested by a Party), samples and reports arising therefrom in accordance with each Research and Technical Development Plan within [***] following completion thereof.

4.2 The Licensee shall provide Ascendis with a draft of each Research and Technical Development Plan. The Licensee shall consider, in good faith, any comments regarding each draft Research and Technical Development Plan that Ascendis provides to the Licensee within [***] of Ascendis' receipt of such draft Research and Technical Development Plan. In addition, the Licensee shall keep Ascendis informed of the progress of the development of each Licensed Product against the applicable Research and Technical Development Plan at each meeting of the JDC pursuant to Clause 4.6(A).

4.3 The Licensee shall use Diligent Efforts to develop and commercialise Licensed Product in the Field and/or Diabetic Retinopathy in the Territory, including, subject to Clause 5.1, using Diligent Efforts to commence Research and Technical Development Plans [***].

4.4 If the Licensee has not commenced Research and Technical Development Plans for [***] such Licensed Products within [***] and Ascendis has complied with Clause 5.1, then the licence granted to the Licensee under Clause 2.1(A) shall become non-exclusive in the Field, except that [***].

4.5 The Licensee shall conduct all development of Licensed Product in compliance with current Good Laboratory Practice, Good Clinical Practice and Good Manufacturing Practice, in each case, where applicable. Neither Party shall use any person that has been debarred, disqualified or banned from practising medicine to perform activities under this Agreement, and each Party shall immediately notify the other Party in writing if any person performing activities under this Agreement is disqualified, debarred or banned from practising medicine.

4.6 **Joint Development Committee**

(A) **Formation of JDC**

Promptly after the Effective Date, the Parties will form a Joint Development Committee comprised of [***] representatives of Ascendis and [***] representatives of the Licensee for the first Research and Technical Development Plan (and will promptly form a JDC following agreement between the Parties in relation to each additional Research and Technical Development Plan).

One representative of the Licensee at the JDC will be selected to act as the chairperson of the JDC. The JDC will meet at least [***] times per year during the term of a Research and Technical Development Plan. Such meetings may be conducted by videoconference, teleconference or in person, as agreed by the Parties. The JDC will agree upon the time and location of the meetings. The chairperson, or his or her designee, will circulate an agenda for each meeting approximately one (1) week before the date scheduled for the meeting, and will include all matters requested to be included on such agenda by either Party. The chairperson, or his or her designee, will take complete and accurate minutes of all discussions occurring at the JDC meetings and all matters decided upon at the meetings except that matters reflecting legal advice of counsel will not be included in such minutes. A copy of the draft minutes of each meeting will be provided to each Party by the chairperson, or his or her designee, after each meeting, and such minutes will be reviewed by the JDC members, any needed changes discussed and final minutes agreed to and provided to each Party within thirty (30) days after each meeting unless otherwise agreed. A reasonable number of additional representatives of a Party may attend meetings of the JDC in a non-voting capacity. Each Party is responsible for its travel costs and expenses associated with attending meetings.

(B) JDC functions and powers

The responsibilities of the JDC will be as follows:

- (1) encouraging and facilitating communication between the Parties with respect to the development of Licensed Products and the Research and Technical Development Plan Activities;
- (2) establishing and revising the applicable Research and Technical Development Plan's objectives, goals and schedules, and reviewing and approving amendments to the applicable Research and Technical Development Plan (including to the applicable Research and Technical Development Plan's budget);
- (3) monitoring, discussing and overseeing the progress of the development of Licensed Products and each Party's progress with respect to the Research and Technical Development Plan Activities for which it is responsible and each Party's diligence in carrying out its responsibilities under the applicable Research and Technical Development Plan; and
- (4) carrying out the other duties and responsibilities described for it in this Agreement.

(C) JDC decision making

All decisions of the JDC will be made by unanimous vote, with each of Ascendis, Genentech and Roche having one vote and the decisions will be recorded in the JDC minutes. If after reasonable discussion and consideration of each of the Parties' views on a particular matter before the JDC, the JDC is unable to reach a decision by unanimous vote on that matter, then [***]; provided, however, that in no event shall [***] such matter in a manner that:

- (1) materially impairs any rights or assets [***];

- (2) results in: (i) increased out-of-pocket costs [***]; or (ii) an increased obligation [***] to utilise any internal resources, in each case unless [***];
- (3) results in a material reallocation of the activities [***] under a Research and Technical Development Plan unless the [***];
- (4) results in a material expansion of the activities, or scope, of [***]; or
- (5) knowingly results in: [***].

The JDC shall not have any authority other than that expressly set forth above and, specifically, shall have no authority: (x) to amend or interpret this Agreement; (y) to determine whether or not a Party has met its diligence or other obligations under the Agreement; or (z) to determine whether or not a breach of this Agreement has occurred.

(D) **Termination of JDC**

The JDC shall terminate in respect of a Research and Technical Development Plan upon completion by both Parties of their respective Research and Technical Development Plan Activities, unless the Parties otherwise agree.

5. **Manufacturing**

- 5.1 During the first [***] after the Effective Date, or for a longer period as may be mutually agreed between the Parties, and in order to enable the initiation of the Licensee's activities under the Research and Technical Development Plans initiated within such [***] after the Effective Date, Ascendis shall, subject to the provisions of this Clause 5.1, use its Diligent Efforts to provide to the Licensee the raw materials for the TransCon Linker and starting materials for placebo TransCon Hydrogel or the placebo TransCon Hydrogel, in each case as necessary for the manufacture of Licensed Product (the "Raw Materials"). The Licensee shall submit a written request to Ascendis, which request shall outline the Licensee's requirements for such Raw Materials, and Ascendis shall, within the timeline mutually agreed by the Parties supply such requirements, subject to the terms of Ascendis' written agreements with Third Party manufacturing organisations and any reasonable requirements of such Third Party manufacturing organisations. The transfer price for Raw Materials shall be [***] to such Third Party manufacturing organisation by Ascendis, and [***].
- 5.2 In addition, for each Research and Technical Development Plan, Ascendis shall assist with identifying: (a) the appropriate linker and/or hydrogel composition; and (b) the associated manufacturing reaction conditions, including selection of protection groups and analytical characterisation for the related Licensed Product ("Product and Release Services"). For each Licensed Product, Ascendis shall provide chemistry, manufacturing and control support pertaining to the up-scaling of Licensed Product ("CMC Services"). Ascendis' activities associated with Product and Release Services and/or CMC Services shall be charged at the Ascendis FTE Rate.

- 5.3 Except as set forth in Clauses 5.1 and 5.2 above, the Licensee shall be solely responsible at its own expense for all technical research and development and Manufacturing of pre-clinical, clinical and commercial quantities of Licensed Product developed under this Agreement in the Field or Diabetic Retinopathy in the Territory.
- 5.4 Ascendis shall provide to the Licensee (and/or any Third Party contracted by the Licensee) all Ascendis Technical Information that is Controlled by Ascendis and/or its Affiliates and is necessary or reasonably useful to enable the Manufacture of the Licensed Product in the Field or Diabetic Retinopathy in the Territory. Ascendis shall provide a sufficient number of personnel hours necessary or useful to enable the Licensee (or a Third Party contracted by the Licensee) to use the Ascendis Technology for such Manufacture. Ascendis' fees for the provision of such Ascendis Technical Information and personnel hours shall be charged at the Ascendis FTE Rate.
- 5.5 The Licensee shall, and it shall procure that its Affiliates and any Sub-Licensees shall:
- (A) ensure that any packaging together with any inserts or material relating to the sale of Licensed Product comply with Applicable Laws and are marked, where required, with all relevant patent numbers of Ascendis Patents and/or Licensed Product Patents; and
 - (B) conduct all packaging and distribution in accordance with current Good Manufacturing Practice.

6. **Regulatory**

- 6.1 The Licensee shall have the sole responsibility for obtaining and maintaining, and shall own, all Regulatory Approvals for Licensed Product developed under this Agreement from Regulatory Authorities in each of the countries in the Territory in the Field or Diabetic Retinopathy.
- 6.2 The Licensee undertakes to comply, and to procure that its Sub-Licensees and contractors comply, with all requirements of Regulatory Authorities and/or applicable law, regulation and guidance.
- 6.3 Ascendis shall provide assistance and information as reasonably requested by the Licensee in support of such regulatory activities, which shall be charged at the Ascendis FTE Rate.

7. **Payments**

7.1 **Upfront**

The Licensee shall pay Ascendis a one-time, non-refundable, upfront payment of Twenty Million US Dollars (\$20,000,000) within [***] of the Effective Date.

7.2 **Research and development funding**

The Licensee shall pay Ascendis the Ascendis Research and Technical Development Plan Expenses in accordance with the Research and Technical Development Plans and Clauses 5 and 6.

7.3 **Development milestones**

(A) The Licensee shall notify Ascendis within [***] of the first satisfaction of the applicable development milestones under sections [***] below, and within [***] of the first satisfaction of the applicable commercialisation milestones under sections [***] below, with the first Licensed Product in a particular Class for each Target.

For example, if the Licensee develops a particular Licensed Product to a Target, which Licensed Product incorporates a Large Molecule, and pays development milestones [***], no payment shall be due under such development milestones on the Licensee’s development of another Licensed Product to the same Target, which Licensed Product incorporates a Large Molecule, including the same or different Large Molecule. Likewise, if the Licensee develops a particular Licensed Product to a Target, which Licensed Product incorporates a Large Molecule, and pays development milestones [***], payment shall be due under such development milestones on the Licensee’s development of another Licensed Product to the same Target, which Licensed Product incorporates a Small Molecule or a Polypeptide.

	Milestones	Amount
(i)	[***]	[***]
(ii)	[***]	[***]
(iii)	[***]	[***]
(iv)	[***]	[***]
(v)	[***]	[***]
(vi)	[***]	[***]
(vii)	[***]	[***]
	Total milestones	[***]

(B) Milestones paid for Other Licensed Products shall be paid at [***] of the amounts indicated in the table above.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (C) Where any development milestone [***] for a Licensed Product in a particular Class and Target is not achieved before the next development milestone is achieved, the sum of the milestone payments due for both the non-achieved and the achieved development milestone shall be paid to Ascendis for such Licensed Product. For example, should a Licensed Product go directly to development milestone [***] without going through development milestone [***], the sum of the milestone payments due for development milestone [***] and development milestone [***] would be payable to Ascendis upon achievement of development milestone [***] for such Licensed Product.
- (D) In any event, the total development milestones shall not exceed [***] per Class and Target for a Ranibizumab Licensed Product and [***] per Class and Target for any Other Licensed Product.
- (E) Following receipt by Ascendis of notice in accordance with Clause 7.3(A), Ascendis shall submit an invoice to the Licensee for the amount of such development milestone payment, and the Licensee shall pay the respective payment for such event within [***] after receipt of such invoice from Ascendis. All invoices shall identify the associated Licensed Product, the fee being invoiced and the description of the milestone event. Unless otherwise requested by the Licensee in writing, Ascendis shall send invoices to Genentech at the address in the preamble of this Agreement, to the attention of Finance Manager, Business Development, M/S 53.

7.4 **Royalty term**

The royalty term for each Licensed Product will begin upon the date of First Commercial Sale of such Licensed Product and will extend, on a Licensed Product-by-Licensed Product and country-by-country basis: (i) for [***] after such First Commercial Sale of such Licensed Product in such country; or (ii) while the use or sale of a Licensed Product would, but for the licences granted by Ascendis herein, infringe a Valid Claim within the Ascendis Patents or Licensed Product Patents in such country, whichever of (i) or (ii) is longer (the “Royalty Term”).

7.5 **Royalty rates**

- (A) During the Royalty Term, in respect of Ranibizumab Licensed Products, the Licensee will pay to Ascendis royalties on Net Sales of all Ranibizumab Licensed Products on the following worldwide cumulative basis:

<u>Annual Net Sales</u>	<u>Royalty rate</u>
That portion of calendar year Net Sales accumulated worldwide greater than [***]	[***]
That portion of calendar year Net Sales accumulated worldwide greater than [***]	[***]
That portion of calendar year Net Sales accumulated worldwide greater than [***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (B) During the Royalty Term, in respect of Other Licensed Products, the Licensee will pay to Ascendis royalties on Net Sales of such Other Licensed Products on the following worldwide cumulative basis:

<u>Annual Net Sales</u>	<u>Royalty rate</u>
That portion of calendar year Net Sales accumulated worldwide greater than [***]	[***]
That portion of calendar year Net Sales accumulated worldwide greater than [***]	[***]
That portion of calendar year Net Sales accumulated worldwide greater than [***]	[***]

- (C) If the Licensee [***] filed on or before [***] on or after [***], and the use or sale of a Licensed Product would, [***] in respect of such Licensed Product shall be reduced by [***] on a Licensed Product-by-Licensed Product and country-by-country basis. For clarity, this reduction shall not apply if: (i) the [***] that is the subject of [***] filed on or after [***] on or after [***]; or (ii) if the [***].
- (D) Royalties payable under this Clause 7.5 for Ranibizumab Licensed Products shall be paid within [***] of the end of each Quarterly Period and for Other Licensed Products shall be paid within [***] of the end of each Quarterly Period, in each case in US Dollars to the credit of a bank account to be designated in writing by Ascendis. The Licensee shall convert the amount of such sales into Swiss Francs and then into US Dollars using the Licensee's then-current internal foreign currency translation actually used on a consistent basis in preparing its audited financial statements.
- (E) At the same time as payment of royalties falls due, the Licensee shall submit, or cause to be submitted, to Ascendis a statement in writing recording the calculation of such royalties payable and in particular:
- (1) the Quarterly Period for which the royalties are calculated;
 - (2) the Sales of each Licensed Product sold during the Quarterly Period;
 - (3) the amount of lump sum deduction as per subpart (1) of the Net Sales definition during the Quarterly Period;
 - (4) the uncollectible amounts as per subpart (2) of the Net Sales definition during the Quarterly Period;

- (5) the amount of credit card charges as per subpart (3) of the Net Sales definition during the Quarterly Period;
 - (6) the amount of government mandated fees and taxes as per subpart (4) of the Net Sales definition during the Quarterly Period;
 - (7) the Net Sales of each Licensed Product sold during the Quarterly Period;
 - (8) the amount of royalties due and payable; and
 - (9) the amount of any withholding or other income taxes deductible or due to be deducted from the amount of royalties due and payable (if applicable).
- (F) Where the Licensee has granted any sub-licence, the Licensee shall include, in its royalty payments, payments in respect of all sales which are carried out by or on behalf of the Sub-Licensee, and shall include records of such sales in the statements it submits pursuant to this Clause 7.5.

7.6 **Royalty reduction for Generic Product**

During the Royalty Term, for sales of Licensed Product where a Generic Product for such Licensed Product is sold in the Field or Diabetic Retinopathy in a particular country in the Territory, the applicable royalty rate in effect with respect to such Licensed Product in such country will be reduced by [***] if the sum of: (a) the Sales of such Licensed Product; and (b) (as applicable) the net sales of such Licensed Product by any Sub-Licensee that is not an Affiliate reported to the Licensee in accordance with the Sub-Licensee's contractual terms and its then currently used accounting standards in such country are reduced by [***] in a Quarterly Period (such Quarterly Period being a "Post-Generic Launch Quarterly Period") compared to the sum of (a) and (b) of such Licensed Product in such country in the equivalent Quarterly Period immediately prior to the launch of the Generic Product (such Quarterly Period being a "Pre-Generic Launch Quarterly Period"); provided that the same principles are applied in the calculation of such sum as are usually and consistently applied by the Licensee and such Sub-Licensee during the consecutive Quarterly Periods between the Pre-Generic Launch Quarterly Period and the Post-Generic Launch Quarterly Period (inclusive). In any event, the applicable royalty rate shall not be less than [***].

7.7 **Third Party licences**

If the Licensee (or its Affiliates or Sub-Licensees) is required to make payments under any agreement entered into with any Third Party for patent or know-how rights to make, have made, use, sell, offer for sale or import a Licensed Product in the Field or Diabetic Retinopathy in a particular country in the Territory, and such Third Party payments are required solely for the Licensee to practise Ascendis Technology claimed in the Ascendis Patents and used or incorporated in such Licensed Product that is being developed and commercialised by the Licensee in such country ("Third Party Licences"), then, on a calendar year, Licensed Product-by-Licensed Product basis, the Licensee may offset against its royalty obligations to Ascendis up to [***] of the amount of such Third Party payment for such calendar year; provided that such offset shall not reduce the applicable royalty rate payable to Ascendis by more than [***] and provided further that, in any event, the applicable royalty rate shall not be less than [***].

7.8 Taxes

In the event that the Licensee is required, under applicable laws, to withhold any deduction or tax from any payment due to Ascendis under this Agreement, such amount shall be deducted from the payment to be made by the Licensee, paid to the proper taxing authority, provided that the Licensee shall take reasonable and lawful actions to avoid and minimise such withholding and promptly notify Ascendis so that Ascendis may take lawful actions to avoid and minimise such withholding. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time-to-time in effect.

All sums payable by the Licensee under or pursuant to this Agreement are exclusive of VAT (if applicable). Accordingly, where any taxable supply for VAT purposes is made under or in connection with this Agreement by Ascendis to the Licensee, the Licensee shall, in addition to any payment required for that supply, pay to Ascendis such VAT as is chargeable in respect of the supply at the same time as payment is due. The Licensee shall provide to Ascendis, prior to the due date for payment or the raising of any invoice (whichever is the earlier), details of the Licensee's own VAT registration number. Ascendis shall provide the Licensee with a valid VAT invoice in respect of any payment of VAT.

7.9 Interest

Where any fees, milestones or other sums payable by the Licensee to Ascendis hereunder remain unpaid after the date on which they became due, the Licensee shall pay to Ascendis interest calculated from the date upon which the sums became due until payment thereof at the rate, to the extent permitted by applicable law, equal to [***].

8. Records and Auditing

8.1 Each Party will maintain complete and accurate books, records and accounts used for the determination of any payment obligations under this Agreement, which books, records and accounts will be retained by such Party until [***] after the end of the period to which such books, records and accounts pertain. The Licensee shall make such books, records and accounts available to Ascendis for [***] if reasonably available and required by the applicable tax authority.

8.2 Each Party will have the right to have an independent certified public accounting firm of internationally recognised standing, reasonably acceptable to the other Party, have access during normal business hours, and upon timely request and at least [***] prior written notice, to such records of the other Party and its Affiliates as may be reasonably necessary to verify the accuracy of any payment made or received for any Quarterly Period ending not more than [***] prior to the date of such request; provided, however, that no Party will have the right to conduct more than one such audit in any [***] or more frequently than once with respect to records covering any specific period of time. The accounting firm will disclose to the Parties only whether the data reported by the audited Party are correct or incorrect and the specific details concerning any discrepancies. The auditing Party will bear all costs of such audit, unless the audit reveals a discrepancy in the auditing Party's favour of more than [***], in which case the audited Party will bear the cost of the audit for the subject period. The accounting firm shall share any draft audit reports with the Licensee before such draft audit reports are shared with the auditing Party and before the final audit report is issued. The Parties shall discuss in good faith any disagreement in respect of the audit report. All information, data, documents and abstracts referred to shall be used only for the purpose of verifying any payment obligation under this Agreement, and shall be treated as the audited Party's Confidential Information subject to use and disclosure restrictions and the confidentiality obligations of this Agreement.

- 8.3 If, based on the results of any audit, additional payments are owed Ascendis under this Agreement, then the Licensee will make such additional payments promptly after the accounting firm's written report is delivered to both Parties. If, based on the results of any audit, any payments made by the Licensee to Ascendis exceeded the amounts due and payable under this Agreement, then Ascendis will return such excess to the Licensee promptly after the accounting firm's written report is delivered to both Parties.
- 8.4 The failure of a Party to request verification of any payment calculation within the period during which corresponding records must be maintained under this Clause 8 will be deemed to be acceptance of the payment and reports for the relevant Quarterly Period.

9. **Pharmacovigilance**

- 9.1 Upon execution of this Agreement, the Parties shall promptly, and in any event before the Licensee starts any clinical development activities, agree on the terms of a safety data exchange agreement (the "SDEA") for the collection, reporting and exchange of safety information. The scope of the SDEA shall also include the Licensee's Affiliates and Sub-Licensees.
- 9.2 Each Party shall notify the other of a "serious adverse experience" or "unexpected adverse experience" (as defined below) and will manage the same, both in accordance with the terms of the SDEA. For the purpose of this Clause 9.2, "serious adverse experience" and "unexpected adverse experience" shall have the meaning assigned by relevant regulations (to the extent applicable). To the extent relevant regulations require harmonisation or are not applicable, then each of the foregoing terms shall be as defined in the SDEA.

10. **Confidentiality**

- 10.1 During the term of this Agreement, and for a period of [***] thereafter, the Licensee agrees to keep secret Ascendis' Confidential Information, to use the same exclusively as permitted under this Agreement, and to disclose the same only to those of its employees, contractors, consultants, Affiliates and Sub-Licensees to whom and to the extent that such disclosure is reasonably necessary in order to exercise its rights and perform its obligations under this Agreement.
- 10.2 During the term of this Agreement, and for a period of [***] thereafter, Ascendis agrees to keep secret the Licensee's Confidential Information, to use the same exclusively as permitted under this Agreement, and to disclose the same only to those of its employees, contractors, Affiliates, Sub-Licensees and licensees to whom and to the extent that such disclosure is reasonably necessary in order to exercise its rights and perform its obligations under this Agreement. Notwithstanding the foregoing, Ascendis shall not use or disclose the Licensee's Confidential Information relating to: [***].

- 10.3 Each Party shall procure that all its employees, contractors, Affiliates and Sub-Licensees who have access to any Confidential Information of the other to which the obligations of Clauses 10.1 or 10.2 as the case may be apply, shall be made aware of, subject to, and comply with those obligations.
- 10.4 The foregoing obligations of Clauses 10.1 and 10.2 shall not apply to any Confidential Information which:
- (A) prior to receipt thereof from one Party was in the possession of the recipient Party and at its free disposal;
 - (B) is subsequently disclosed to the recipient Party without any obligations of confidence by an independent Third Party who has not derived it directly or indirectly from the disclosing Party;
 - (C) is or becomes generally available to the public through no act or default of the recipient Party or its agents, contractors or employees; or
 - (D) is independently developed by the receiving Party without the benefit of any disclosure hereunder, as demonstrated by documented evidence prepared contemporaneously with such independent development.
- 10.5 Notwithstanding the foregoing, a Party and its Affiliates and Sub-Licensees may use and disclose the Confidential Information of the other Party:
- (A) if it is required to be disclosed by law, regulation or action of any governmental agency or authority, including as may be required in connection with any filings made with, or by the disclosure policies of a major stock exchange; provided that the Party seeking to disclose the Confidential Information of the other Party: (i) uses commercially reasonable efforts to inform the other Party prior to making any such disclosures and cooperates with the other Party in seeking a protective order or other appropriate remedy (including redaction); and (ii) whenever it is possible to obtain confidential treatment, request confidential treatment of such information;
 - (B) as reasonably necessary to obtain or maintain any regulatory approval, including to conduct preclinical studies and clinical trials and for pricing approvals, for any Licensed Products, provided that, the disclosing Party shall use commercially reasonable efforts to limit disclosure of the Confidential Information outside such regulatory agency and to otherwise maintain the confidentiality of the Confidential Information; or
 - (C) to take any lawful action that it deems necessary to protect its interest under, or to enforce compliance with the terms and conditions of, this Agreement.
- 10.6 The Licensee and its Affiliates and Sub-Licensees may disclose the Confidential Information of Ascendis to contractors, consultants and other service providers in connection with the development or manufacture of Licensed Products under conditions of confidentiality at least as restrictive as those contained in this Clause 10 and/or as is standard for similar deals in the biotechnology industry. The Licensee may disclose a copy of this Agreement to Chugai for the purpose of verifying its interest in being included as an Affiliate under this Agreement.
- 10.7 Each Party ("Publishing Party") shall submit to the other Party manuscripts, including abstracts, and texts of poster presentations and other external presentations containing the other Party's Confidential Information at least [***] prior to presentation or submission for publication for purposes of allowing the other Party to comment on the manuscript or text; provided that the other Party may require the Publishing Party, by giving notice in writing to the Publishing Party within [***] of the receipt of such manuscript, abstract, text or other external presentations from the Publishing Party to redact certain information or delay submission for publication or presentation of such manuscript, abstract, text or other external presentation if, in the reasonable opinion of the other Party such delay is necessary in order to permit the filing of any patent application or to protect the other Party's Confidential Information contained in such manuscript, abstract, text or other external presentation.

- 10.8 [***], in accordance with its internal policies and procedures, shall have the right to publish all studies, clinical trials and results thereof on the clinical trial registries that are maintained by or on behalf [***]. [***] any studies, clinical trials or results thereof on its clinical trial registry, provided however, that [***].
- 10.9 Notwithstanding the foregoing, each Party shall have the right to disclose the terms and conditions of this Agreement: (i) in confidence (i.e., pursuant to a written confidentiality agreement containing terms at least as stringent as those contained in this Agreement) to any bona fide potential or actual investor, investment banker, auditor, counsel, acquirer or merger target; and (ii) subject to the prior written consent of the other Party, such consent not to be unreasonably withheld, for the purpose of a public offering or private placement of shares and/or securities.

11. **Intellectual Property and Improvements**

- 11.1 All Patents and Technical Information and other Intellectual Property owned by a Party prior to the Effective Date shall remain the sole property of the respective Party.
- 11.2 Ascendis and the Licensee acknowledge and agree that as between them:
- (A) Ascendis (or its Affiliates) shall own all right, title and interest in and to any and all Licensed Product Patents filed before the Effective Date (including any patent applications claiming priority to such Licensed Product Patents), Ascendis Patents, Ascendis Technical Information and Ascendis Improvements;
 - (B) the Licensee shall own all right, title and interest in and to any and all Licensee Technology, Licensee Improvements and Process Inventions, and any Licensed Product Patents filed on or after the Effective Date; and
 - (C) the Licensee and Ascendis (or its Affiliates) shall each own an undivided fifty per cent (50%) right, title and interest in and to any and all Joint Improvements. For the avoidance of doubt, subject to the licences granted under this Agreement, each Party shall be free to exploit, transfer or encumber its own interest in the Joint Improvements without the consent of, and without accounting to, the other Party.

12. **Prosecution, Maintenance and Defence**

- 12.1 Ascendis shall [***] and in its sole discretion, be responsible for filing, prosecuting, maintaining and defending the Ascendis Patents and any Patent claiming Ascendis Technology or Ascendis Improvements. In respect of any such Patents that are necessary or useful to make, have made, use, sell, offer for sale or import a Licensed Product, and which are added by Ascendis to Part 1 of Schedule 1, Ascendis will provide the Licensee with drafts of all proposed filings and correspondence (including without limitation the initial application as well as any material correspondence with any Intellectual Property Office related to any filings) in a manner that allows the Licensee a reasonable opportunity for review and comment before such filings are made or due. Ascendis will consider all of the Licensee's reasonable suggestions, recommendations and instructions concerning the preparation, filing, prosecution, defence and maintenance of any such Patents (including without limitation any suggestion or recommendation to alter or limit the scope, content and/or claims of any such application), provided that such reasonable suggestions, recommendations and instructions are provided to Ascendis within [***] of the Licensee receiving any such proposed filings and correspondence. If Ascendis does not wish to file, prosecute or maintain any such Patent or if Ascendis wishes to allow any such Patent to lapse, it shall offer in writing to Licensee an opportunity to acquire such Patent(s) with the right to use such Patent(s) as it wishes, without compensation to Ascendis.

12.2 The Licensee shall [***] and in its sole discretion, be responsible for filing, prosecuting, maintaining and defending any Licensed Product Patent or any Patent claiming Licensee Technology, Licensee Improvements and/or Process Inventions. If the Licensee does not wish to file, prosecute, maintain or defend any Licensed Product Patent and/or any Patent claiming Process Inventions, or if the Licensee wishes to allow any such Patent to lapse, it shall offer in writing to Ascendis an opportunity to file, prosecute, maintain or defend such Patent at Ascendis' own expense and in Ascendis' sole discretion.

12.3 Joint Improvements

- (A) The Parties shall select a mutually agreed upon outside patent counsel ("Outside Patent Counsel") to file, prosecute and maintain any Patent claiming a Joint Improvement in the joint names of the Parties ("Joint Improvement Patent"). Licensee shall have the first right, at its sole expense and in its sole discretion, to engage Outside Patent Counsel to file, prosecute and maintain Joint Improvement Patents and Ascendis shall have the second right in accordance with Clause 12.3(C). The Party that engages Outside Patent Counsel to file, prosecute and maintain a particular Joint Improvement Patent shall be referred to as the "Prosecuting Party".
- (B) With respect to Joint Improvement Patents, the Prosecuting Party shall, or shall instruct Outside Patent Counsel to: (1) keep both Parties informed as to the filing, prosecution and maintenance such that each Party has sufficient time to review and comment on any documents intended for submission to any Intellectual Property Office; (2) promptly furnish to each Party a copy of any patent application and copies of documents relevant to prosecution and maintenance for review and comment; and (3) reasonably consider and incorporate comments of both Parties on documents files with any Intellectual Property Office.
- (C) If the Licensee elects: (1) not to file, prosecute or maintain a Joint Improvement Patent (whether worldwide or with respect to any particular country); or (2) to allow any such Patent to lapse or become abandoned or unenforceable, then the Licensee shall notify Ascendis in writing at least [***] prior to the lapse or abandonment of any such Patent. Thereafter, Ascendis may, but is not required to, undertake[***] and in its sole discretion, the prosecution and maintenance of such Joint Improvement Patent.
- (D) The Parties agree to cooperate reasonably in the filing, prosecution and maintenance of all Patents under this Clause 12.3 including providing relevant Technical Information to the Prosecuting Party, obtaining and executing necessary powers of attorney and assignments by the named inventors, obtaining execution of such other documents which may be needed in the filing, prosecution and maintenance of each such Patent, and, as requested, updating each other regarding the status of each such Patent, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession and Control that is reasonably necessary to prosecute and maintain such Patents.

13. **Enforcement of Patent Rights and Defence of Third Party Claims**

13.1 **Infringement by a Third Party**

- (A) In the event of Ascendis or the Licensee becoming aware of any suspected infringement or any unauthorised use by a Third Party of any of the Ascendis Patents, Ascendis Technical Information, Ascendis Improvements, Licensee Technology, Licensee Improvements, Process Inventions, Licensed Product Patents and/or the Joint Improvements in the Field or Diabetic Retinopathy in the Territory, the Party becoming aware of the same shall notify the other Party.
- (B) Where such suspected infringement or unauthorised use is of the Ascendis Patents, Ascendis Technical Information and/or Ascendis Improvements, in each case outside the Field, Ascendis shall, [***], have the exclusive right, but not the obligation, to take or threaten any legal action that it deems appropriate to halt such suspected infringement and to [***] in respect of such suspected infringement or unauthorised use. Termination and/or settlement of the litigation are at the sole discretion of Ascendis (i.e., without the prior consent of the Licensee).
- (C) Where such suspected infringement or unauthorised use is of the Licensed Product Patents, Ascendis Patents, Ascendis Technical Information and/or any Ascendis Improvements, in each case, Controlled by Ascendis, in each case in the Field, the Licensee shall, at its own expense, have the first right, but not the obligation to take or threaten any legal action that it deems appropriate to halt such suspected infringement. Each Party shall retain the following per cent of any remaining amounts recovered in respect of such suspected infringement or unauthorised use after the Licensee has recouped its expenses: the Licensee shall retain [***] and Ascendis shall retain [***]. Termination and/or settlement of the litigation are [***].
- (D) If Ascendis wishes to take or threaten legal action and the Licensee has the first right to do so under Clause 13.1(C), but does not do so within [***] of becoming aware of potential infringement, then Ascendis may take or threaten such legal action and the Licensee shall, at Ascendis' request, lend its name where necessary or desirable to proceedings relating to such action and provide reasonable assistance in such proceedings. In such circumstances, Ascendis shall have conduct of the action but shall consult the Licensee in good faith with regard to significant decisions. Each Party shall retain the following per cent of any remaining amounts recovered in respect of such suspected infringement or unauthorised use after Ascendis has recouped its expenses: then Ascendis shall retain an amount equal to [***] and the Licensee shall retain the remaining [***]. Termination and/or settlement of the litigation are [***].

13.2 **Defence of Third Party Claims**

- (A) In the event that the development or commercialisation of a Licensed Product results in action by a Third Party against a Party (or its Affiliates or Sub-Licensees) for infringement or unauthorised use of Intellectual Property or confidential information anywhere in the Territory, such Party shall promptly notify the other Party in writing.
- (B) Each Party (or its Affiliates or Sub-Licensees) against whom such action is brought shall: (i) have the right but not the obligation to defend such action; (ii) have the right to be represented by separate legal advisors; (iii) keep the other Party informed of, and assist and co-operate with the other Party in, any such action; and (iv) bear its own costs.

14. **Warranties**

14.1 Each Party warrants to the other Party that it:

- (A) is free to enter into this Agreement and to carry out its obligations hereunder without violating any obligation owed by it or any of its Affiliates to any Third Party;
- (B) shall not, during the existence of this Agreement, enter into any assignments, licences, obligations, charges or assignments, either written, oral or implied, which are or shall be inconsistent with this Agreement;
- (C) has obtained all necessary corporate approvals to enter into and execute this Agreement;
- (D) has never been debarred, disqualified or banned from practising medicine and that it is not under investigation by any Regulatory Authority for debarment, disqualification or any similar regulatory action in any country.

14.2 Ascendis represents and warrants to the Licensee that, as of the Effective Date, Ascendis:

- (A) Controls the Ascendis Patents and Ascendis Technical Information in the Field in the Territory;
- (B) has the right to grant to the Licensee the rights and licences granted to the Licensee under the terms and conditions of this Agreement, including, without limitation, the right and licence for the Licensee to use the Licensed Product Patents, Ascendis Patents and/or Ascendis Technical Information to research, develop and commercialise non-exclusively a Licensed Product in Diabetic Retinopathy under the terms and conditions of this Agreement;
- (C) has the right to provide and disclose to the Licensee the Ascendis Technical Information that it provides or discloses to the Licensee under the terms and conditions of this Agreement;
- (D) has not received notice of any actions, lawsuits, claims or arbitration or material adverse proceedings (other than on-going routine patent prosecution matters) in any way relating to the Ascendis Patents, Ascendis Technical Information or Ascendis Technology; and
- (E) save as disclosed to the Licensee, is not, to the best of its knowledge, aware that the use of the Licensed Product Patents listed in Part 1 of Schedule 1, Ascendis Patents listed in Part 2 of Schedule 1 and/or Ascendis Technical Information listed in Schedule 2, for development or commercialisation of a Licensed Product infringes any Third Party's Patent.

- 14.3 EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO INTELLECTUAL PROPERTY RIGHTS OR CONFIDENTIAL INFORMATION SUPPLIED BY IT TO THE OTHER PARTY HEREUNDER, AND EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT.
15. **Indemnification**
- 15.1 Except as provided in Clause 15.2 below, the Licensee shall indemnify, defend and hold harmless Ascendis and its Affiliates, and their respective directors, officers, employees and agents (each an “Ascendis Indemnatee”) from and against all Losses arising out of or resulting from any Third Party Claims to the extent such Losses result from or arise out of: (a) the activities performed by the Licensee in connection with the exercise of its rights or obligations under this Agreement; or (b) breach by the Licensee of the representations and warranties provided in Clause 14. The indemnification obligations set forth in this Clause 15.1 shall not apply to the extent that any such Third Party Claim arose or resulted from the gross negligence, recklessness or wilful misconduct of any Ascendis Indemnitees.
- 15.2 Except as provided in Clause 15.1 above, Ascendis shall indemnify, defend and hold harmless the Licensee, its Affiliates, and their respective directors, officers, employees and agents (each a “Licensee Indemnatee”) from and against all Losses arising out of or resulting from any Third Party Claims to the extent such Losses result from or arise out of: (a) the activities performed by Ascendis in connection with the exercise of its rights or obligations under this Agreement; or (b) breach by Ascendis of the representations and warranties provided in Clause 14. The indemnification obligations set forth in this Clause 15.2 shall not apply to the extent that any such Third Party Claim arose or resulted from the gross negligence, recklessness or wilful misconduct of any Licensee Indemnitees.
- 15.3 In the event that an Ascendis Indemnatee or a Licensee Indemnatee, as applicable (hereinafter an “Indemnified Party”) seeks indemnification under this Clause 15, such Indemnified Party shall: (i) give prompt notice to the indemnifying Party of any such Third Party Claim; (ii) permit the indemnifying Party to assume direction and control of the defence of such Third Party Claim (including decisions regarding its settlement or other disposition, which may be made in the indemnifying Party’s sole discretion except as otherwise provided herein); (iii) assist the indemnifying Party at the indemnifying Party’s expense in defending such Third Party Claim; and (iv) not compromise or settle such Third Party Claim without the indemnifying Party’s prior written consent, which shall not be unreasonably withheld or delayed. The failure to deliver written notice to the indemnifying Party within a reasonable time after the commencement of any such Third Party Claim, to the extent prejudicial to its ability to defend such Third Party Claim, shall relieve the Indemnifying Party of any obligation to the Indemnified Party under this Clause 15. The Indemnified Party may participate in the defence of such Third Party Claim through counsel of its choice, but the reasonable cost of such counsel shall be borne solely by the Indemnified Party. It is understood that only Ascendis or the Licensee may claim indemnity under this Clause 15 (on its own behalf or on behalf of its Indemnified Parties), and other Indemnified Parties may not directly claim indemnity hereunder. No compromise or settlement of any Third Party Claim may be effected by the indemnifying Party without the Indemnified Party’s prior written consent (which consent shall not be unreasonably withheld or delayed), unless: (a) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnified Party; (b) the sole relief provided is monetary damages that are paid in full by the indemnifying Party; and (c) the Indemnified Party’s rights under this Agreement are not adversely affected. The Indemnified Party shall have no right to settle any such Third Party Claim without the prior written consent of the indemnifying Party (and any such settlement without the prior written consent of the indemnifying Party shall relieve the indemnifying Party of its obligations under this Clause 15), unless: (x) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnifying Party; (y) the sole relief provided is monetary damages that are paid in full by the Indemnified Party; and (z) the indemnifying Party’s rights under this Agreement are not adversely affected.

16. **Limitation of Liability**

16.1 Subject to Clause 16.2, neither of the Parties nor any of their Affiliates shall be liable to each other under any contract, negligence, strict liability or other legal or equitable theory for indirect, incidental, special, punitive, exemplary or consequential damages arising out of or resulting from this Agreement. The foregoing shall not limit:

- (A) the obligations of either Party from and against Third Party claims under Clauses 15.1 or 15.2 to the extent that such Third Party has been awarded such damages; or
- (B) the liability of a Party as a result of its breach of Clause 10.

16.2 Neither Party limits or excludes its liability for fraud, fraudulent concealment or fraudulent misrepresentation, nor for death or personal injury arising from its negligence.

16.3 Genentech and Roche shall be jointly and severally liable as the Licensee under this Agreement.

17. **Term and Survival**

17.1 This Agreement shall commence with effect from the Effective Date and shall continue for so long as the Licensee is required to make payments under Clause 7, unless terminated earlier pursuant to Clause 18.

17.2 On the expiration or other termination of this Agreement each Party shall continue to be bound by 9.2 (Pharmacovigilance), 10 (Confidentiality), 15 (Indemnification), 16 (Limitation of Liability), 17 (Term and Survival), 19 (Effect of Termination), 20 (Dispute Resolution) and 21 (Miscellaneous).

18. **Termination**

18.1 **Licensee termination for convenience**

The Licensee may terminate this Agreement at any time for any reason:

- (A) as a whole, by giving ninety (90) days' prior written notice to Ascendis; or
- (B) on a Licensed Product-by-Licensed Product basis, by giving: (i) ninety (90) days' prior written notice prior to the First Commercial Sale of the applicable Licensed Product; and (ii) one hundred and eighty (180) days' written notice after the First Commercial Sale of the applicable Licensed Product, provided that any Licensed Product with respect to which the Agreement is terminated shall thereafter be excluded from the licence to the Licensee under Clause 2.1 and from the restrictions imposed on Ascendis and its Affiliates under Clause 2.3.

18.2 Mutual termination for material breach and Severe Material Breach

- (A) Except as set forth in Clause 18.2(B), in the event that either Party commits a material breach of any of the terms of this Agreement on its part to be performed or observed, the other Party shall have the right to terminate this Agreement, as a whole or on a Licensed Product-by-Licensed Product basis for the Licensed Product that was the subject of the breach, by giving sixty (60) days' written notice to the defaulting Party; provided, however, that in the case of a material breach capable of being made good, if the defaulting Party shall make good such material breach within sixty (60) days after the notice has been given, then the notice shall not be effective and the Agreement shall not terminate.
- (B) In the event that either Party commits a Severe Material Breach on its part to be performed or observed, the other Party shall have the right to terminate this Agreement, as a whole or on a Licensed Product-by-Licensed Product basis for the Licensed Product that was the subject of the breach, by giving thirty (30) days' written notice to the defaulting Party; provided, however, that in the case of a Severe Material Breach capable of being made good, if the defaulting Party shall make good such Severe Material Breach within thirty (30) days after the notice has been given, then the notice shall not be effective and the Agreement shall not terminate.

18.3 Mutual termination for bankruptcy and other bankruptcy matters

To the extent legally possible:

(A) Right to terminate

A Party (the "Non-Bankrupt Party") may, in addition to any other remedies available to it by law or in equity, terminate this Agreement, in whole or on a Licensed Product-by-Licensed Product basis as it may determine, by notice to the other Party (the "Bankrupt Party"), in the event the Bankrupt Party has become bankrupt, has made an assignment for the benefit of its creditors or there has been appointed a trustee or receiver of the Bankrupt Party for all or a substantial part of its property or any case or proceeding shall have been commenced or other action taken by or against the Bankrupt Party in bankruptcy or seeking reorganisation, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganisation or other similar act or law of any jurisdiction now or hereafter in effect and any such event shall have continued for sixty (60) days undischarged, unbonded and undischarged.

(B) Retention of rights

All rights and licences granted under or pursuant to this Agreement by the Bankrupt Party to Non-Bankrupt Party are, and shall otherwise be deemed to be, for purposes of paragraph 365(n) of the United States Bankruptcy Code, licences of rights to "intellectual property" as defined under paragraph 101(35A) of the United States Bankruptcy Code. The Parties agree that the Non-Bankrupt Party, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code. The Parties further agree that in the event of the commencement of a bankruptcy proceeding by or against the Bankrupt Party, including under the United States Bankruptcy Code, the Non-Bankrupt Party shall be entitled to complete access to any such intellectual property of the Bankrupt Party that pertains to the rights granted in the licenses under this Agreement and embodiments of such intellectual property.

18.4 **Licensee termination for Change of Control**

The Licensee may terminate this Agreement as a whole, effective immediately upon written notice to Ascendis, in the event of a Change of Control in favour of a Competitor which does not segregate Ascendis' personnel and activities under this Agreement from the Competitor so that such Competitor is a Third Party for the purposes of this Agreement (e.g., with respect to access to Confidential Information) [***].

18.5 **Ascendis termination for Patent challenge**

Ascendis may terminate this Agreement, as a whole or on a Licensed Product-by-Licensed Product basis, effective immediately upon written notice to the Licensee, if the Licensee challenges in a court the validity, enforceability or scope of any Ascendis Patent or Licensed Product Patent, unless Ascendis or its Affiliates has initiated or participated in a legal proceeding against the Licensee or its Affiliates in which an Ascendis Patent or Licensed Product Patent is asserted against the Licensee or its Affiliate in connection with activities of the Licensee or its Affiliate, and such challenge is in defence of such legal proceeding.

19. **Effect of Termination**

19.1 The termination of this Agreement shall be without prejudice to:

- (A) the obligation of the Licensee to pay to Ascendis all sums accrued, due and payable under Clause 7 as of the effective date of termination; and
- (B) any right of, or remedy available to, either Party against the other in respect of anything done or omitted hereunder prior to such termination.

19.2 **Termination by the Licensee**

(A) **For Convenience**

In the event of termination of this Agreement in whole or in part by the Licensee pursuant to Clause 18.1:

- (1) the licences granted to Ascendis and its Affiliates under Clause 2.2 shall survive (along with all obligations associated therewith); and
- (2) the licences granted to the Licensee and its Affiliates under Clause 2.1:
 - (a) if the Licensee terminates in part, shall terminate for the applicable Licensed Product(s) as of the effective date of such termination and all other licences granted to the Licensee and its Affiliates under Clause 2.1 shall survive (along with all obligations associated therewith) with respect to any other Licensed Product(s); or
 - (b) if the Licensee terminates in whole, shall terminate as of the effective date of such termination.

(B) **For Ascendis' breach or bankruptcy**

In the event of termination of this Agreement in whole by the Licensee pursuant to Clauses 18.2(A) or 18.3(A), subject to Clause 19.6:

- (1) the licences granted to the Licensee and its Affiliates under Clause 2.1 shall survive (along with all obligations associated therewith) in respect of any Licensed Product Patents, Ascendis Patents, Ascendis Technical Information, Ascendis Improvements and Ascendis' and its Affiliates' interest in Joint Improvements that exist as of the effective date of such termination;
- (2) the licences granted to Ascendis and its Affiliates under Clause 2.2 shall survive (along with all obligations associated therewith) in respect of any Licensed Product Patents, Process Inventions and the Licensee's and its Affiliates' interest in Joint Improvements that exist as of the effective date of such termination;
- (3) Ascendis shall [***];
- (4) if the effective date of such termination is prior to the [***] of the Effective Date, unless otherwise agreed to by the Licensee, Ascendis' obligations under Clauses 5.1 and 5.2 shall survive until the [***] of the Effective Date; and
- (5) Ascendis' and its Affiliates' obligations under Clause 2.3 shall survive until the [***] of the effective date of such termination.

In the event of termination of this Agreement by the Licensee in respect of a particular Licensed Product pursuant to Clauses 18.2(A) or 18.3(A), this Clause 19.2(B) applies in respect of such terminated Licensed Product only and this Agreement shall continue in respect of all other Licensed Product(s) which are not terminated.

(C) **For Ascendis' Severe Material Breach**

In the event of termination of this Agreement in whole by the Licensee pursuant to Clause 18.2(B), subject to Clause 19.6:

- (1) the licences granted to the Licensee and its Affiliates under Clause 2.1 shall survive (along with all obligations associated therewith) in respect of any Licensed Product Patents, Ascendis Patents, Ascendis Technical Information, Ascendis Improvements and Ascendis' and its Affiliates' interest in Joint Improvements that exist as of the effective date of such termination;
- (2) the licences granted to Ascendis and its Affiliates under Clause 2.2 shall survive (along with all obligations associated therewith) in respect of any Licensed Product Patents, Process Inventions and the Licensee's and its Affiliates' interest in Joint Improvements that exist as of the effective date of such termination;

- (3) Ascendis shall [***];
- (4) the Licensee's obligations under Clauses 4.1 to 4.4 (inclusive) shall terminate, and any and all other diligence or reporting obligations of the Licensee shall cease;
- (5) if the effective date of such termination is prior to the [***] of the Effective Date, unless otherwise agreed to by the Licensee, Ascendis' obligations under Clauses 5.1 and 5.2 shall survive until the [***] of the Effective Date;
- (6) Ascendis' and its Affiliates' obligations under Clause 2.3 shall survive until the [***] of the effective date of such termination; and
- (7) the Licensee shall [***] pending the outcome of any arbitration proceeding pursuant to Clause 20.2; provided that [***].

In the event of termination of this Agreement by the Licensee in respect of a particular Licensed Product pursuant to Clause 18.2(B), this Clause 19.2(C) applies in respect of such terminated Licensed Product only and this Agreement shall continue in respect of all other Licensed Product(s) which are not terminated.

19.3 Termination by Ascendis

In the event of termination of this Agreement in whole or in part by Ascendis pursuant to Clauses 18.2, 18.3 or 18.5, subject to Clauses 19.5 and 19.6:

- (A) the licences granted to Ascendis and its Affiliates under Clause 2.2 shall survive (along with all obligations associated therewith);
- (B) Ascendis' and its Affiliates' obligations under Clause 2.3 shall cease; and
- (C) the licences granted to the Licensee and its Affiliates under Clause 2.1:
 - (1) if Ascendis terminates in part, shall terminate for the applicable Licensed Product(s) as of the effective date of such termination and all other licences granted to the Licensee and its Affiliates under Clause 2.1 shall survive (along with all obligations associated therewith) with respect to any other Licensed Product(s); or
 - (2) if Ascendis terminates in whole, shall terminate as of the effective date of such termination.

19.4 **Change of Control**

In the event of termination of this Agreement in whole by the Licensee pursuant to Clause 18.4:

- (A) the Competitor that acquires Ascendis shall not be deemed to be an Affiliate for the purpose of this Agreement;
- (B) the licences granted to the Licensee and its Affiliates under Clause 2.1 shall survive (along with all obligations associated therewith) in respect of any Licensed Product Patents, Ascendis Patents, Ascendis Technical Information, Ascendis Improvements and Ascendis' (or its successor Entity's) and its Affiliates' interest in Joint Improvements, in each case that exist as of the effective date of such termination;
- (C) the licences granted to Ascendis (or its successor Entity) and its Affiliates under Clause 2.2 shall survive (along with all obligations associated therewith) in respect of any Licensed Product Patents, Process Inventions and the Licensee's and its Affiliates' interest in Joint Improvements, in each case that exist as of the effective date of such termination;
- (D) Ascendis (or its successor Entity) shall [***];
- (E) the Licensee's obligations under Clauses 7.2 to 7.9 and Clause 19.7 shall survive and, subject to Clause 17.2, any and all other obligations of the Licensee and Ascendis (or its successor Entity) under this Agreement shall terminate as of the effective date of such termination;
- (F) if the effective date of such termination is prior to the [***] of the Effective Date, unless otherwise agreed to by the Licensee, Ascendis' (or its successor Entity's) obligations under Clause 5.1 shall survive until the [***] of the Effective Date; and
- (G) Ascendis' (or its successor Entity's) and its Affiliates' obligations under Clause 2.3 shall survive until the [***] of the effective date of such termination.

19.5 **Inventory at termination**

In the event this Agreement is terminated for any reason, the Licensee shall have the right to sell or otherwise dispose of Licensed Products then in its stock, subject to the applicable royalty payments due under Clauses 7.4 to 7.7, and any other applicable provisions of this Agreement, and Ascendis covenants not to sue the Licensee for infringement under any Patents with respect to such activities conducted by the Licensee pursuant to this 19.5.

19.6 **Continuation of sub-licences**

Upon termination of this Agreement, any existing, permitted sub-licence granted by a Party under this Agreement shall continue in full force and effect, provided that the permitted Sub-Licensee did not cause the breach that gave rise to a termination under Clause 18.2 and agrees to be bound by all the terms and conditions of this Agreement that are applicable to such permitted Sub-Licensee, including, without limitation, rendering directly to the licensing Party all payments and other obligations due to the licensing Party related to such sub-licence.

19.7 **Return of Confidential Information**

Following any expiration or termination of this Agreement, the Party that has Confidential Information of the other Party shall return to the other Party (or destroy at such Party's written request) all such Confidential Information in its possession as of the effective date of expiration or termination (with the exception of one copy of such Confidential Information, which may be retained by the legal department of the Party that received such Confidential Information to confirm compliance with the non-use and non-disclosure provisions of this Agreement, and any Confidential Information of the other Party contained in its laboratory notebooks or databases.

20. **Dispute Resolution**

20.1 **Internal resolution**

- (A) Any dispute, controversy or claim related to matters within the powers and authority of the JDC shall be resolved by the Parties in accordance with procedures set forth in Clause 4.6.
- (B) Except as otherwise expressly provided herein, including in Clause 20.1(A) above, in the event of any controversy, claim or other dispute arising out of or relating to compliance with this Agreement, or the validity, breach, termination or interpretation of this Agreement, such dispute shall be first referred to the Executives for resolution, prior to proceeding under the following provisions of Clause 20.2. A dispute shall be referred to the Executives upon one Party providing the other Party with written notice that such dispute exists, and the Executives shall attempt to resolve such dispute through good faith discussions. In the event that the Executives cannot resolve such dispute within thirty (30) days of such other Party's receipt of such written notice, either Party may initiate the dispute resolution procedures set forth in Clause 20.2. The Parties agree that any discussions between such Executives, or their designees, regarding such dispute shall be the Confidential Information of both Parties and do not constitute settlement discussions, unless the Parties agree otherwise in writing.

20.2 **Arbitration**

Except as otherwise expressly provided in this Agreement, the Parties agree that any dispute not resolved internally by the Parties pursuant to Clause 20.1(B), shall be resolved through binding arbitration conducted under the auspices of the International Chamber of Commerce in accordance with the then prevailing Rules of Arbitration of the International Chamber of Commerce (for purposes of this Clause 20.2, the "Rules"), except as modified in this Agreement, applying the substantive law specified in Clause 21.12 (Governing law). A Party may initiate arbitration by written notice to the other Party of its intention to arbitrate, and such demand notice shall specify in reasonable detail the nature of the dispute. Each Party shall select one (1) arbitrator, and the two (2) arbitrators so selected shall choose a third arbitrator. All three (3) arbitrators shall serve as neutrals and have at least ten (10) years of: (a) dispute resolution experience (including judicial experience); and/or (b) legal or business experience in the biotech or pharmaceutical industry. In any event, at least one (1) arbitrator shall satisfy the foregoing experience requirement under Clause 20.2(b). Notwithstanding anything to the contrary in this Clause 20.2, in the event of a dispute regarding the Prosecution and Maintenance activities described in Clause 12 at least one (1) arbitrator shall have expertise in patent law. If a Party fails to nominate its arbitrator, or if the Parties' arbitrators cannot agree on the third arbitrator,

the necessary appointments shall be made in accordance with the Rules. Once appointed by a Party, such Party shall have no *ex parte* communication with its appointed arbitrator. The arbitration proceedings shall be conducted in Frankfurt, Germany. The arbitration proceedings and all pleadings and written evidence shall be in the English language. Any written evidence originally in another language shall be submitted in English translation accompanied by the original or a true copy thereof. Each Party agrees to use commercially reasonable efforts to make all of its current employees available, if reasonably needed, and agrees that the arbitrators may deem any party as "necessary." The arbitrators shall be instructed and required to render a written, binding, non-appealable resolution and award on each issue that clearly states the basis upon which such resolution and award is made. The written resolution and award shall be delivered to the Parties as expeditiously as possible, but in no event more than ninety (90) days after conclusion of the hearing, unless otherwise agreed by the Parties. Judgment upon such award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such an award and order for enforcement. Each Party agrees that, notwithstanding any provision of applicable law or of this Agreement, it will not request, and the arbitrators shall have no authority to award, punitive or exemplary damages against any Party. The Parties may apply to any court of competent jurisdiction for a temporary restraining order, preliminary injunction or other interim or conservatory relief, as necessary, without breaching these arbitration provisions and without abridging the powers of the arbitrators. At the request of either Party, the arbitrators shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings. The arbitrators shall have the power to decide all questions of arbitrability. The Parties agree that: (i) they shall share equally the fees and expenses of the arbitrators; and (ii) each Party shall bear its own attorneys' fees and associated costs and expenses.

20.3 **Patent validity**

Notwithstanding the other provisions of this Clause 20, any dispute that involves the validity, infringement or claim interpretation of a Patent that is issued: (a) in the United States shall be subject to actions before the United States Patent and Trademark Office and/or submitted exclusively to the federal court located in the jurisdiction of the district where any of the defendants resides; and (b) in any other country shall be brought before an appropriate regulatory or administrative body or court in that country, and the Parties hereby consent to the jurisdiction and venue of such courts and bodies. For the sake of clarity, such Patent disputes shall not be subject to the provisions of Clause 20.2. Nothing in this Agreement shall be construed to prevent the Licensee from disputing or challenging the validity of a Third Party's Patent.

21. **Miscellaneous**

21.1 **General assurances**

At any time after the date hereof each of the Parties shall, at the request and cost of the other Party, execute or procure the execution of such documents and do or procure the doing of such acts and things as the Party so requiring may reasonably require for the purpose of giving to the Party so requiring the full benefit of all the provisions of this Agreement, subject to any express restrictions in this Agreement on the extent of either Party's obligations under this Agreement. This includes in particular (without prejudice to the generality of the foregoing) entry into forms of licence or other instruments confirming such rights for registration with appropriate Intellectual Property Offices (including in the form set out in Schedule 4), Regulatory Authorities and other authorities in the Territory.

21.2 **Unenforceability and severability**

If any of the provisions of this Agreement are held to be void or unenforceable, then such void or unenforceable provisions shall be replaced by valid and enforceable provisions that will achieve as far as possible the economic business intentions of the Parties. However, the remainder of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e. the Parties would presumably have concluded this Agreement without the unenforceable provisions.

21.3 **Assignments**

Neither this Agreement nor any of the rights and obligations created herein is assignable or transferable by either Party without the prior written consent of the other, such consent not to be unreasonably withheld or delayed.

Notwithstanding the preceding sentence, Ascendis is entitled to assign this Agreement and/or any rights created herein to, subject to the assumption of the obligations herein by, any Affiliate of Ascendis or any purchaser of the whole or a substantial part of the business of Ascendis. For the avoidance of doubt, the Parties agree that the Ascendis Technology constitutes a substantial part of the business of Ascendis.

21.4 **Rights cumulative and other matters**

- (A) The rights, powers, privileges and remedies provided in this Agreement are cumulative and are not exclusive of any rights, powers, privileges or remedies provided by law or otherwise.
- (B) No failure to exercise nor any delay in exercising by any Party to this Agreement of any right, power, privilege or remedy under this Agreement shall impair or operate as a waiver thereof in whole or in part.
- (C) No single or partial exercise of any right, power privilege or remedy under this Agreement shall prevent any further or other exercise thereof or the exercise of any other right, powers, privilege or remedy.

21.5 **Costs of preparation**

The Parties hereto shall pay their own respective legal costs incurred in the preparation of this Agreement.

21.6 **Entire Agreement and variation**

- (A) This Agreement, together with any documents referred to in it, constitutes the whole agreement between the Parties relating to its subject matter and supersedes and extinguishes any prior drafts, agreements, undertakings, representations, warranties and arrangements of any nature, whether in writing or oral, relating to such subject matter. All information related to the subject matter of this Agreement previously exchanged under the Research Collaboration Agreement, the Confidentiality Agreement and the Feasibility Study Agreement shall be protected under Clause 10 of this Agreement as if disclosed under this Agreement.
- (B) Each Party acknowledges that it has not been induced to enter into this Agreement by any representation or warranty other than those contained in this Agreement and, having negotiated and freely entered into this Agreement, agrees that it shall have no remedy in respect of any other such representation or warranty except in the case of fraud.

(C) No variation of this Agreement shall be effective unless made in writing and signed by each of the Parties.

21.7 **Notices and invoices**

- (A) Any notice (which term shall in this Clause 21.7 include any communication) required to be given under this Agreement or in connection with the matters contemplated by it shall, except where otherwise specifically provided, be in writing in the English language.
- (B) Any such notice shall be addressed as provided in Clause 21.7(C) and may be:
- (1) personally delivered, in which case it shall be deemed to have been given upon delivery at the relevant address if it is delivered not later than 17.00 hours on a Business Day, or, if it is delivered later than 17.00 hours on a Business Day or at any time on a day which is not a Business Day, at 08.00 hours on the next Business Day;
 - (2) sent by pre-paid registered airmail, or by air courier in which case it shall be deemed to have been given seven (7) Business Days after the date of posting in the case of registered airmail or two (2) Business Days after delivery to the courier, in the case of air courier;
 - (3) sent by electronic mail, in which case it shall be deemed to have been given when sent from the electronic mail exchange, provided that any notice sent by electronic mail after 17.00 hours on any Business Day or at any time on a day which is not a Business Day shall be deemed to have been given at 08.00 on the next Business Day.
- (C) The addresses and other details of the Parties referred to in this Clause 21.7(C) are, subject to Clause 21.7(D):

Ascendis' address:

Ascendis Pharma Ophthalmology Division A/S
Tuborg Boulevard 12
DK-2900 Hellerup
Denmark

Email: [***]

Attention: [***]

Genentech's address:

Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080
USA

Attention: Corporate Secretary

With a required copy to:

Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080
USA

Attention: VP, Genentech Partnering

Roche's address:

Grenzacherstrasse 124
4070 Basel
Switzerland

Attention: Group Legal Department

(D) Either Party to this Agreement may notify the other Party of any change to the address or any of the other details specified in Clause 21.7, provided that such notification shall only be effective on the date specified in such notice or five (5) Business Days after the notice is given, whichever is later.

(E) **Invoices**

All invoices that are required or permitted under this Agreement shall be in writing and sent by Ascendis to the Licensee at the address provided under Clause 7.3(E).

21.8 Force Majeure

Neither Party to this Agreement shall be deemed to be in breach of this Agreement or otherwise liable to the other as a result of any delay or failure in the performance of its obligations under this Agreement if and to the extent that such delay or failure is caused by Force Majeure, and the time for performance of the relevant obligation(s) shall be extended accordingly. The Party concerned shall promptly notify the other Party of the nature and effect of such event and both Parties shall, where the same is practicable, use Diligent Efforts to minimise such effect and to comply with the respective obligations herein contained as nearly as may be in their original form, provided that if the Force Majeure event continues for a period of ninety (90) days or more following notification, the Party not affected by the event may terminate this Agreement by giving not less than thirty (30) days prior notice to the other Party.

21.9 Relationship of the Parties

- (A) Nothing in this Agreement shall constitute, or be deemed to constitute, a partnership between the Parties nor, except as expressly provided, shall it constitute, or be deemed to constitute, any Party the agent of any other Party for any purpose.
- (B) Subject to any express provisions to the contrary in this Agreement, neither Party shall have any right or authority to and shall not do any act, enter into any contract, make any representation, give any warranty, incur any liability, assume any obligation, whether express or implied, of any kind on behalf of the other Party or bind the other Party in any way.

21.10 Counterparts

This Agreement may be executed in any number of counterparts, which shall together constitute one Agreement. Any Party may enter into this Agreement by signing any such counterpart.

21.11 Third Party rights

No person who is not a party to this Agreement shall have any right to enforce any term of this Agreement.

21.12 Governing law

This Agreement shall be governed by and construed in accordance with the laws of Germany without reference to its conflict of laws principles, and shall not be governed by the United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention).

[Signature page follows]

AS WITNESS the Parties hereof have executed this Agreement the day and year first before written.

Signed by
for and on behalf of
ASCENDIS PHARMA
OPHTHALMOLOGY DIVISION A/S

) /s/ Michael Wolff Jensen
) Michael Wolff Jensen
) Chairman
)

/s/ Jan Møller Mikkelsen
Jan Møller Mikkelsen
CEO

Signed by
for and on behalf of
GENENTECH, INC.

) /s/ Robert E. Andreatta
) Robert E. Andreatta
) VP, Finance, Controller + CAO

Signed by
for and on behalf of
F. HOFFMANN-LA ROCHE LTD

) /s/ Dr. Sophie Kornowski-Bonnet
) Dr. Sophie Kornowski-Bonnet
) Global Head of Roche Partnering

Signed by
for and on behalf of
F. HOFFMANN-LA ROCHE LTD

) /s/ Dr. Melanie Frey Wick
) Dr. Melanie Frey Wick
) Authorized Signatory

SCHEDULE 1 : PATENTS

Part 1: Licensed Product Patents

[***]

Part 2: Ascendis Patents

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE 2: TECHNICAL INFORMATION

The following list describes the Ascendis Technical Information that Ascendis will provide to the Licensee pursuant to Clause 3.1:

[***]

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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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SCHEDULE 3: EXCLUDED INDICATIONS

Part I:

Diabetes

“Diabetes” means [***].

Diabetes-Related Metabolic Disorders

“Diabetes-Related Metabolic Disorders” means [***].

“Diabetic Dyslipidemia” means [***].

“Fatty Liver Disease” means [***].

“Metabolic Syndrome” means the presence of [***] of the following:

- (A) [***]
- (B) [***]
- (C) [***]
- (D) [***]
- (E) [***]

as such criteria may be modified or completed by applicable treatment and/or regulatory guidelines in force from time to time in the relevant country(ies).

Obesity

“Obesity” means ***

Part II:

***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE 4 : SHORT FORM PATENT LICENCE

THIS AGREEMENT is made the [] day of []

BETWEEN:

- (1) **ASCENDIS PHARMA OPHTHALMOLOGY DIVISION A/S**, (“Ascendis”), a company registered in Denmark with its registered office at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark; and
 - (2) **GENENTECH, INC.**, (“Genentech”), a Delaware corporation with its principal place of business at 1 DNA Way, South San Francisco, CA 94080, USA; and
 - (3) **F. HOFFMANN-LA ROCHE LTD**, (“Roche”), a company registered in Switzerland with its registered office at Grenzacherstrasse 124, 4070 Basel, Switzerland.
- (Genentech and Roche, together the “Licensee”)

Ascendis and the Licensee are each a “Party”, and together the “Parties”, to this agreement.

Ascendis hereby grants to the Licensee an exclusive licence for exploitation of the patent(s) set out in the Appendix below worldwide for the treatment and/or prevention of any disease, condition or disorder of the eye and adnexa, defined according to WHO ICD (but non-exclusive for Diabetic Retinopathy), subject to and terminable in accordance with the terms and conditions of an agreement between the Parties hereto dated 31 July 2013.

Appendix

[insert details of relevant patents/patent applications]

AS WITNESS the Parties have executed this agreement the day and year first above written.

Signed by)
for and on behalf of)
ASCENDIS PHARMA)
OPHTHALMOLOGY DIVISION A/S)

Signed by)
for and on behalf of)
GENENTECH, INC.)

Signed by)
for and on behalf of)
F. HOFFMANN-LA ROCHE LTD)

Signed by)
for and on behalf of)
F. HOFFMANN-LA ROCHE LTD)

*** Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXECUTION COPY

Patent Transfer & Exclusive Licence Agreement

between

Ascendis Pharma A/S
as Licensor

and

Sanofi-Aventis Deutschland GmbH
as Licensee

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BETWEEN:

- (1) **ASCENDIS PHARMA A/S**, (“Licensor” or “Ascendis”), a company registered in Denmark with its registered office at Tuborg, Boulevard 12, DK-2900 Hellerup, Denmark; and
- (2) **SANOFI AVENTIS DEUTSCHLAND GmbH**, (“Licensee” or “Sanofi”), a company registered in Germany with its registered office at Industriepark Höchst 65926 Frankfurt am Main, Germany.

Each a “Party” and together the “Parties”.

Background:

- (A) Ascendis owns and controls proprietary rights, titles and interests in patents and technical information relating to Glp-1 and Glp-1 analogs, exendin-4 and exendin-4 analogs, glucagon and glucagon analogs, insulin and insulin analogs and the TransCon technology platform.
- (B) Sanofi wishes to develop and to commercialise Glp-1 and Glp-1 analogs, exendin-4 and exendin-4 analogs, glucagon and glucagon analogs, insulin and insulin analogs and other products in and outside the field of diabetes and certain diabetes-related metabolic disorders using the TransCon technology platform, and Ascendis wishes to sell certain patents rights to Sanofi and grant Sanofi certain exclusive or non-exclusive, worldwide, licences in respect of certain other patent rights, on the terms and conditions of this Agreement.

THE PARTIES AGREE THAT:

1. Interpretation

1.1 Definitions

“Affiliate” means any business Entity which from time to time Controls, is Controlled by or is under common Control with a Party to this Agreement.

“Ascendis Development Plan Expenses” means the following costs and expenses incurred by Ascendis after the Effective Date directly in connection with Ascendis’ activities in accordance with the Development Plan:

- (a) out-of-pocket costs associated with the conduct of any development activities performed by Ascendis, its Affiliates or by an Independent Third Party on behalf of Ascendis in accordance with the Development Plan (and for clarity are not otherwise included as part of the Ascendis FTE Rate);
- (b) Ascendis FTE Costs; and
- (c) any other costs or expenses specifically identified and included in the Development Plan, which, for the avoidance of doubt may include, without limitation, pre-paid amounts.

“Ascendis FTE Costs” means, for all activities performed by Ascendis or its Affiliates in accordance with the Development Plan or as otherwise directed in writing by Sanofi, the product of (i) the number of FTEs used by Ascendis or its Affiliates for such activities as set forth in the Development Plan or other written document approved by Sanofi and (ii) the Ascendis FTE Rate. For the avoidance of doubt, [***].

“Ascendis FTE Rate” means [***] per FTE, which amount is fully burdened and includes without limitation, for each FTE, [***].

“Ascendis Improvement” means any Improvement which is developed, in-licensed, acquired or otherwise controlled by Ascendis or its Affiliates after the Effective Date.

“Business Day” means a day (other than a Saturday or Sunday) on which banks are open for ordinary face to face banking business in Copenhagen, Frankfurt/Main and Paris.

“Business Team” means three (3) personnel of Ascendis and/or its Affiliates, having the scientific, technical and business skills, expertise and experience necessary to conduct the Ascendis Development Activities in accordance with the terms hereof. The names of the members of the Business Team as of the Effective Date are listed on Part I of schedule 6.

“Control(led)(ling)” means the beneficial ownership of more than fifty per cent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management of the company, partnership or other Entity in question.

“Cover(ed)(ing)” means, with respect to any Patent and the subject matter at issue, that, but for a licence granted under a Valid Claim of such Patent, the manufacture, development, use, sale, offer for sale or importation of the subject matter at issue would infringe such Valid Claim, or in the case of a Patent that is patent application, would infringe a Valid Claim in a patent issued from such patent application if the currently pending claims of such patent application were to be issued as a patent.

“Development Plan” means the technology transfer and development activities to be performed by Ascendis and Affiliates and the associated timetable and Ascendis Development Plan Expenses to such activities. A preliminary overview of the Development Plan is set out in Schedule 4. No later than [***] after the Effective Date, the Parties will discuss in good faith and agree on a detailed Development Plan description to be attached to this Agreement as an update of Schedule 4. The Development Plan may be amended from time to time by the JDC during the term hereof.

“Diabetes” means [***].

“Diabetes-Related Metabolic Disorders” means [***].

“Diabetic Dyslipidemia” means [***].

***] or (ii) as may be defined in applicable treatment and/or regulatory guidelines in force from time to time in the relevant country(ies).

“Diligent Efforts” means with respect to a Party the level of efforts and resources such Party would typically exert in similar circumstances pursuing the development and commercialisation of a similar product with similar market potential taking into account the stage of development or commercialization, market potential and market size, the product life cycle, the risk of development or commercialization of the Product, the cost effectiveness of efforts or resources, the competitiveness of alternative products that are or are expected to be in the marketplace, the scope and duration of patent rights or other proprietary rights related to the Product, the profitability of the Product and alternative products and other relevant commercial factors. The efforts of each Party’s respective Affiliates and Sub-Licensees shall count towards that Party’s own Diligent Efforts.

“Effective Date” means the date of this Agreement.

“EMA” shall mean the European Medicines Agency or any successor agency with comparable responsibilities.

“Entity” means, and includes, any person, firm or company or group of persons or unincorporated body.

“Fatty Liver Disease” means ***].

“Glp-1 Product” means ***].

“Glucagon Product” means ***].

“Good Clinical Practice” means the applicable principles and guidelines for good clinical practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time to time, including without limitation those set out in the Harmonised Tripartite Guideline for Good Clinical Practice as finalised by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

“Good Laboratory Practice” means the applicable principles and guidelines for good laboratory practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time to time, including without limitation those set out in the OECD Principles of Good Laboratory Practice published by the Organisation for Economic Co-Operation and Development.

“Good Manufacturing Practice” means all applicable principles and guidelines for good manufacturing practice for drugs and medicinal products, as such principles and guidelines are amended, implemented and supplemented from time to time, including without limitation as specified in the applicable provisions of (i) European Directive 2003/94/EC and further guidance as published by the European Commission in Volume IV of “The rules governing medicinal products in the European Community” and (ii) Title 21 Parts 210 and 211 of the US Code of Federal Regulations (21 C.F.R., parts 210 and 211).

“Improvement” means any improvement, discovery, invention, development, enhancement, modification, technical information, whether or not patentable, relating to Product and/or the Technology Platform as in existence on the Effective Date, that arises during the term of this Agreement, that a Party owns or for which it has a licence to any related patent, know-how or intellectual property right and has the ability to grant to the other Party access, a licence or a sub-licence (as applicable) to such patent, know-how or intellectual property right on the terms and conditions set forth herein without violating the terms of any agreement or other arrangement with any Independent Third Party existing at the time such Party would be required hereunder to grant to the other Party such access, licence or sub-licence. For clarity, any products acquired or licensed by either Party from any Independent Third Party after the Effective Date shall not be an Improvement.

“IND” means an investigational new drug application, as defined in 21 C.F.R. Section 312.3, obtained for purposes of conducting clinical trials in accordance with the requirements of the United States Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, including all supplements and amendments thereto; or the equivalent application to the EMA, the filing of which is necessary to commence clinical testing of the Products in humans.

“IND Approval” means the approval of an IND by EMA, FDA or other competent regulatory authority.

“Independent Third Party” means any Entity other than Ascendis, its Affiliates or its Sub-Licensees or Sanofi, its Affiliates or its Sub-Licensees.

“Insulin Product” means [***].

“Initiation” of a Phase II or Phase III Trial shall mean dosing of the first patient with Product or matching placebo (as applicable) in such Phase II or Phase III Trial.

“Intellectual Property Office” means the official local patent, trade mark or other intellectual property registry in each part of the Territory responsible for granting, maintaining records of, patents, trade marks or other intellectual property and any instruments made in respect thereof.

“Joint Improvements” means any Improvements conceived or generated jointly during the term of, and in connection with, this Agreement by employees, agents, or service providers of both Ascendis and Sanofi or their respective Affiliates. Ascendis and Sanofi shall each own an undivided fifty per cent (50%) interest in any Joint Improvement.

“Major Country” means [***].

“Manufacture” or “Manufacturing” means any manufacturing activity of any Product, or any ingredient thereof, including manufacturing for clinical use or commercial sale, testing, handling, packaging and storage, ongoing stability tests and regulatory activities related to any of the foregoing.

“Marketing Authorisation” means the authorisation issued by the relevant Regulatory Authority necessary to place on the market Product in any country or regulatory jurisdiction, but for the avoidance of doubt shall not include pricing and reimbursement approvals or inclusion on the official list of reimbursable drugs.

“Metabolic Syndrome” means the presence of [***] of the following:

- (A) [***]
- (B) [***]
- (C) [***]
- (D) [***]
- (E) [***]

as such criteria may be modified or completed by applicable treatment and/or regulatory guidelines in force from time to time in the relevant country(ies).

“Net Sales” means, with respect to a given period of time, the gross amount invoiced by Sanofi and its Affiliates, its Sub-Licensees and their distributors to bona fide Independent Third Party purchasers from the sale or distribution to bona fide Independent Third Parties of Product, provided such Product is covered by a Valid Claim, less the following deductions and offsets:

- (A) normal and customary trade, cash and quantity discounts, allowances and credits actually allowed or paid, based on the invoiced price or net price to Independent Third Party purchasers, including cash coupons and retroactive price reductions;
- (B) credits or allowances actually granted for damaged Products, returns or rejections of Product, price adjustments and billing errors, in each case not in excess of the selling price of the Product;
- (C) reasonable and customary rebates, charge backs and discounts (or equivalents thereof), based on the invoiced price or net price to Independent Third Party purchasers, granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), federal, state/provincial, local and other governments, their agencies and purchasers and reimbursers;

- (D) transportation costs, including insurance, for outbound freight related to delivery of the Products to the extent billed separately on the invoice and paid by the buyer; and
- (E) sales taxes and other governmental charges (including value added tax, but solely to the extent not otherwise creditable or reimbursed) to the extent billed separately on the invoice and actually paid in connection with the sale (but excluding what is commonly known as income taxes).

The methodology for calculating (A) – (E), on a country-by-country basis, shall conform to IFRS consistently applied by Sanofi and its Affiliates across its product lines.

In the event a Product is sold in combination with one or more other pharmaceutically active ingredient(s), Net Sales shall be calculated [***].

With respect to any Product that includes [***].

For clarity, the [***] where Sanofi, or its Affiliate or Sub-Licensee has [***].

For clarity, the following shall not be included in “Net Sales”: (a) Products transferred for administration to patients enrolled in clinical trials or distributed through a not-for-profit foundation at no charge to eligible patients, and (b) Product used as samples to promote additional Net Sales, in amounts consistent with normal business practices of Sanofi or its Affiliates or Sub-Licensees.

“Non-Proprietary Peptide” means a Peptide which can be freely used without infringing third party rights.

“Obesity” means [***] as may be modified or completed by applicable treatment and/or regulatory guidelines in force from time to time in the relevant country(ies).

“Patents” means the Product Patents, the Technology Platform Patents and any patent that may in the future Cover an Ascendis Improvement or a Joint Improvement.

“Peptide” means a polypeptide of [***].

“Phase II Trial” means, with respect to a Product, any human clinical trial conducted in any country that is designed (i) to evaluate the efficacy of the pharmaceutical product for a particular indication or indications in patient volunteers with the indication under study and to assess side effects or (ii) to support an additional Phase II Trial or any Phase III Trial.

“Phase III Trial” means, with respect to a Product, any human clinical trial conducted in any country after preliminary evidence suggesting acceptable efficacy and safety of the pharmaceutical product has been obtained in prior studies, which is intended to gather additional information to evaluate the overall safety and efficacy of the pharmaceutical product and provide an adequate basis for physician labelling.

“Product” means (i) any product developed by Sanofi incorporating (in whole or part) the Technology Platform and/or using the Product Patents and/or the Technology Platform Patents and/or any Ascendis Improvements and/or any Joint Improvements, and/or (ii) any Glp-1 Product, any Glucagon Product or any Insulin Product or any combination of Glp-1 Product, Glucagon Product, Insulin Product and/or any product included within (i) above.

“Product Patents” means the patents and patent applications listed in Part I of schedule 1 and any conversion, continuation, division, or substitution thereof, and any patents issuing thereon, any reissues, re-examinations or extensions of such patents and any foreign counterparts of such patent applications and patents in any country in the Territory.

“Product Technical Information” means the Technical Information owned or controlled by Ascendis relating specifically to Product.

“Regulatory Approval” means all necessary approvals (including Marketing Authorisations, pricing and reimbursement approvals and inclusion on the official list of reimbursable drugs, as applicable) for the sale of Product for one or more indications in a country or regulatory jurisdiction.

“Regulatory Authority” means any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in any jurisdiction in the Territory involved in the granting of Regulatory Approval for, or involved in the regulation of, pharmaceutical products.

“Sanofi Improvement” means any Improvement conceived or generated solely by employees, agents or service providers of Sanofi or its Affiliates, excluding (i) any Sanofi Medical Device and (ii) any Improvements in Manufacturing.

“Sanofi Medical Device” means any instrument, apparatus, appliance, material or other article proprietary or exclusively licensed to Sanofi, including any existing software necessary for its proper application, and used by Sanofi to administer a pharmaceutical product in humans or animals.

“Sub-Licensee” means any Entity that has been granted a sub-licence by either Party of its rights granted hereunder in accordance with Clause 2.5.

“Technical Information” means all identifiable know-how, experience, data and other information in the possession or control of a Party and which such Party is free to disclose to the other Party, whether in human or machine readable form and whether stored electronically or otherwise and which might reasonably be of commercial, scientific, technical, regulatory or medical interest to the other Party for the research, development, marketing, manufacture, importation, distribution, sale and/or use of product and/or Products and/or the use of Technology Platform.

“Technology Platform” means the Technical Information proprietary to Ascendis (but not including any Product Technical Information or Product Patents), which [***].

“Technology Platform Patents” means the patents and patent applications listed in Part II of Schedule 1 and any conversion, continuation, division, or substitution thereof, and any patents issuing thereon, any reissues, re-examinations or extensions of such patents and any foreign counterparts of such patent applications and patents in any country in the Territory.

“Territory” means worldwide.

“Trade Sale” means a sale (direct or indirect, either through merger or otherwise) to an Independent Third Party (excluding a financial investor provided such financial investor is not affiliated to a pharmaceutical or biotechnology company) of (i) fifty per cent (50%) or more of the shares in Ascendis or (ii) the whole or substantial part of the business of Ascendis. For clarity, the Parties agree that the Technology Platform constitutes a substantial part of the business of Ascendis.

“Transaction” means any transaction relating to the Technology Platform [***]; but excluding (i) [***], and/or (ii) any licensing of the Technology Platform and/or Technology Platform Products by Ascendis for use on any Independent Third Party’s proprietary products [***].

“Valid Claim” means a claim of [***] that (i) has not been rejected, revoked or held to be invalid or unenforceable by a court or other authority of competent jurisdiction, from which decision no appeal can be further taken or (ii) has not been finally abandoned, disclaimed or admitted to be invalid or unenforceable through reissue or disclaimer.

“VAT” means value added tax as provided for in the Value Added Tax Act 1994 and legislation supplemental thereto, TVA or any other system of value added tax as provided for in Council Directive 2006/112/EC applied in any Member State of the European Union and any other similar turnover, sales or purchase, tax or duty levied by any other jurisdiction whether central, regional or local.

1.2 Construction

In this Agreement where the context admits:

- (A) references to any statute or statutory provisions shall be deemed to refer to those provisions as amended or re-enacted or as their application is modified by other provisions from time to time and any reference to a statutory provision shall include any subordinate legislation made from time to time under that provision;
- (B) references to this Agreement or to any other agreement or document referred to in this Agreement mean this Agreement or such other agreement or document as may be amended, varied, supplemented, modified or novated from time to time, and include the Schedules;
- (C) references to Clause(s) and Schedule(s) are references to Clause(s) and Schedule(s) of and to this Agreement, and each of the Schedules shall have effect as if set out in this Agreement;

- (D) the headings and sub-headings in this Agreement are inserted for convenience only and shall not affect the construction of this Agreement;
- (E) the singular includes the plural and vice versa, and references to the masculine, feminine and the neuter shall include all such genders;
- (F) references to any Party include its successors and permitted assigns;
- (G) where any statement is to the effect that Ascendis is not aware of any matter or circumstance, or is a statement qualified by the expression “so far as Ascendis is aware”, such statement shall refer to the state of the actual knowledge of the Business Team or of any other officer or key employee of Ascendis or its Affiliates, after reasonable investigation.
- (H) the symbol “€” means the lawful currency of the member states of the European Union that adopt the single currency in accordance with the EC Treaty, known as the “Euro”; and
- (I) throughout this Agreement, where the context permits, Ascendis shall mean Ascendis and its Affiliates.

2. Sale, Purchase and Licence Grant

- 2.1 Ascendis hereby sells, assigns and transfers to Sanofi all right, title and interest in and to the Product Patents. Sanofi accepts such sale assignment and transfer. Ascendis shall as promptly as practicable after the Effective Date (and no later than [***] thereafter), provide all declarations and sign, deliver and file all documents (or procure that such documents are signed, delivered and filed) that are necessary for the assignment and transfer of the Product Patents and/or their re-registration in the name of Sanofi or a Sanofi Affiliate. Any costs associated solely with effectuating the assignment and transfer of the Product Patents shall be borne by Sanofi.
- 2.2 Subject to the terms and conditions contained herein, Sanofi hereby grants to Ascendis and its Affiliates a non-exclusive, royalty-free, licence (with the right to sub-license subject to Clause 2.5) in the Territory under any Sanofi Improvements and its interest in any Joint Improvements to research, develop, market, manufacture, import, distribute, sell and use products (excluding any Product) outside Diabetes.
- 2.3 Subject to the terms and conditions of this Agreement, Ascendis hereby grants to Sanofi:
 - (A) an exclusive (even as to Ascendis), royalty-free, licence (with the right to grant sub-licences subject to Clause 2.5) in the Territory to the Technology Platform Patents, the Technology Platform, the Ascendis Improvements and its interest in the Joint Improvements to research, develop, market, manufacture, import, distribute, sell and use:
 - (1) Glp-1 Product, Glucagon Product, Insulin Product and any combination of Glp-1 Product, Glucagon Product and/or Insulin Product for all diseases in humans and animals.
 - (2) Products (other than Glp-1 Product, Glucagon Product, Insulin Product and any combination of Glp-1 Product, Glucagon Product and/or Insulin Product) for Diabetes in humans and animals.

- (B) a non-exclusive, royalty-free licence (with the right to grant sub-licences subject to Clause 2.5) in the Territory to the Technology Platform Patents, the Technology Platform, the Ascendis Improvements and its interest in the Joint Improvements to research, develop, market, manufacture, import, distribute, sell and use Products (other than Glp-1 Product, Glucagon Product, Insulin Product and any combination of Glp-1 Product, Glucagon Product and/or Insulin Product) for Diabetes-Related Metabolic Disorders and Obesity in humans and animals, provided that:
- (1) if such Products are Peptides, they must first be developed by Sanofi for Diabetes or Obesity in humans and animals and the first Marketing Authorisation for such Products must be for Diabetes or Obesity in humans in a Major Country; provided, however, that the foregoing shall not prevent Sanofi from developing such Products in Diabetic Related Metabolic Disorders before having completed development in Diabetes or Obesity.
 - (2) if such Products are not Peptides, they must first be developed by Sanofi for Diabetes in humans and animals and the first Marketing Authorisation for such Product must be for Diabetes in humans in a Major Country; provided, however, that the foregoing shall not prevent Sanofi from developing such Products in Diabetic Related Metabolic Disorders before having completed development in Diabetes.

For clarity, the licences granted in Clause 2.3 do not include [***] and Products (other than Glp-1 Product, Glucagon Product, Insulin Product and any combination of Glp-1 Product, Glucagon Product and/or Insulin Product) for use within the cardiovascular, oncology, ophthalmology, digestive systems and/or CNS areas, provided that nothing shall prevent Sanofi from researching, developing, marketing, manufacturing, importing, distributing, selling and using (i) Glp-1 Product, Glucagon Product, Insulin Product and any combination of Glp-1 Product, Glucagon Product and/or Insulin Product in accordance with Clause 2.3(A)(1), or (ii) Product (other than Glp-1 Product, Glucagon Product, Insulin Product and any combination of Glp-1 Product, Glucagon Product and/or Insulin Product) for Diabetes in accordance with Clause 2.3(A)(2) or for any Diabetes Related Metabolic Disorders and/or Obesity in accordance with Clause 2.3(B). For further clarity, nothing in this Agreement shall prohibit Ascendis or its Affiliates, Sub-Licensees or licensees from researching, developing, marketing, manufacturing, importing, distributing, selling and using any product (other than Glp-1 Product, Glucagon Product, Insulin Product and any combination of Glp-1 Product, Glucagon Product and/or Insulin Product) for [***] and/or, for the avoidance of doubt, any Diabetes Related Metabolic Disorders and/or Obesity.

2.4 The licence granted to Sanofi in Clause 2.3(B)(1) shall become exclusive on a Peptide by Peptide basis in respect of a specified Non-Proprietary Peptide if the following conditions are met:

- (A) Sanofi notifies Ascendis [***] for such Non-Proprietary Peptide;
- (B) Sanofi has been engaged [***] in respect of such Non-Proprietary Peptide in Diabetes or Obesity for at least a [***] period immediately preceding such notification, [***] to be justified and documented by Sanofi;

- (C) Ascendis notifies Sanofi in writing that:
- (1) Ascendis, its Affiliates and Sub-Licensees have not [***] in respect of a such Non-Proprietary Peptide for at least a [***] period immediately preceding notification from Sanofi pursuant to Clause 2.4(A), such [***] to be justified and documented by Ascendis; or
 - (2) Ascendis has not granted a licence to such Non-Proprietary Peptide to a bona fide Independent Third Party prior to notification from Sanofi pursuant to Clause 2.4(A);
- such notification to be provided by Ascendis within [***] of notification from Sanofi pursuant to Clause 2.4(A);

provided that nothing in this Clause 2.4 shall be deemed to change the scope of the licence granted in Clause 2.3.

Following conversion of such licence to an exclusive licence in respect of such Non-Proprietary Peptide, if Sanofi abandons the development of such Non-Proprietary Peptide, such licence shall become non-exclusive. In the event that Ascendis has declined Sanofi's request for an exclusive licence for a Non-Proprietary Peptide and Ascendis subsequently abandons the development of such Non-Proprietary Peptide, Sanofi shall then be entitled to an exclusive licence to such Non-Proprietary Peptide.

2.5 Each Party agrees that:

- (A) any and all sub-licences granted under Clauses 2.2 and 2.3 shall be on terms consistent with the terms of this Agreement, contain obligations on each Sub-licensee to perform and observe terms and conditions similar to those contained herein so far as the same are applicable;
- (B) it shall be liable to the other Party for any acts and omissions of any its Sub-Licensee that cause any breach of the provisions of this Agreement; and
- (C) it shall, within thirty (30) days of the grant of each sub-licence, provide the other Party with a copy of such sub-licence, provided that the financials may be redacted.

2.6 Ascendis shall, at the request and expense of Sanofi and where necessary, execute a formal licence agreement substantially in the form set out in schedule 2 and provide reasonable assistance to Sanofi for the purpose of registering the exclusive patent licences granted pursuant to Clause 2.3 in respect of each patent at each relevant Intellectual Property Office in the Territory. For clarity, no compensation shall be due to Ascendis upon the execution of any such formal licence agreement, other than reimbursement of Ascendis' documented expenses.

2.7 Sanofi's Right of Information. During the term of this Agreement, Ascendis shall inform Sanofi about its research and development activities relating to the Technology Platform. Such information shall take place during the meetings of the JDC for the term of the Development Plan, and thereafter [***]. The purpose of such information meetings shall be for Sanofi to be timely informed about any opportunity that may appear to extend the relationship with Ascendis, including in connection with any proposed Transaction or Trade Sale. Prior to accepting any offer received from any Independent Third Party in relation to any Transaction, Ascendis shall first notify Sanofi in writing of the existence of such offer and Sanofi shall be free to submit an offer to Ascendis. Ascendis shall consider in good faith any offer received from Sanofi, and within a reasonable period of time shall indicate to Sanofi whether it is interested in pursuing discussions towards a potential Transaction with Sanofi. Any information received further to this Clause 2.7 shall remain subject to the confidentiality requirements set out in Clause 10. For clarity, nothing in this Clause 2.7 may be interpreted as an obligation on Ascendis to disclose to Sanofi any information that is subject to any confidentiality obligation from time to time owed to any Independent Third Party.

- 2.8 **Immunity from Suit.** Sanofi hereby grants to Ascendis a free right (the “**Immunity**”) to practise any patent that may be applied for, filed by or delivered to Sanofi Covering an Improvement relating to Manufacturing (a “**Manufacturing Patent**”) and/or an Improvement relating to any medical device that is not a Sanofi Medical Device (“**Medical Device Improvement Patent**”) outside Diabetes. The term of the Immunity shall be for the duration of such Manufacturing Patent or Medical Device Improvement Patent, as applicable. The Immunity shall be transferable and/or extendable by Ascendis only to its licensees and/or Sub-Licensees for activities and products outside Diabetes, without any right for such licensees or Sub-Licensees to themselves transfer or extend the Immunity to another party, including by way of business purchase, merger or otherwise. Ascendis shall promptly inform Sanofi in writing after completion of any such transaction with such licensees and/or Sub-Licensees involving a transfer or extension by Ascendis of the Immunity hereby granted, and such notice shall include the identity of such licensees and/or Sub-Licensees and a description of the therapeutic field (but not the financial terms) of the licences granted. For clarity, the Immunity hereby granted to Ascendis does not create any obligation on Sanofi to disclose to Ascendis any Technical Information relating to a Manufacturing Improvement or to a Sanofi Medical Device.
- 2.9 **Non-compete:** During the term of this Agreement, and subject to expiry or termination of this Agreement, Ascendis shall not directly or indirectly engage, either by itself or on behalf of any Independent Third Party, in any research, development or commercialization activities in connection with [***]. Subject to Clause 2.7, this Clause 2.9 shall not apply in respect of [***].
- 3. Technical Information**
- 3.1 Within [***] of the Effective Date, Ascendis shall supply to Sanofi a copy of all Technical Information in Ascendis’ possession or control that is relevant to the Products and Diabetes in the Territory and that has been disclosed to Sanofi up to and including on the Effective Date. Such Technical Information shall at least include the elements listed on schedule 3 and may be supplied in parts.
- 3.2 Upon request from Sanofi at any time and from time to time during the term of this Agreement, Ascendis will use its commercially reasonable efforts to provide Sanofi, or any Affiliate or Independent Third Party designated by Sanofi, with any additional Technical Information relevant to the Products and Diabetes in the Territory in Ascendis’ possession or with on-site support as may be reasonably requested by Sanofi.

- 3.3 Ascendis shall supply to Sanofi any Technical Information which comprises Ascendis Improvements and is relevant to the Products and Diabetes in the Territory, promptly after such Technical Information becomes available to Ascendis during the term of this Agreement.
- 3.4 Nothing herein shall prevent Ascendis, its Affiliates or licensees from using any Technical Information including without limitation a right but not a obligation to use or refer (free of charge) to any regulatory or other data forming part of any Technical Information among other things for the purposes of any regulatory filings provided that such use is not inconsistent with the rights of Sanofi granted hereunder.
- 3.5 Notwithstanding the foregoing, and for the purpose of the licence granted to Ascendis under Clause 2.2, Sanofi will supply to Ascendis a copy of all Technical Information which comprises Sanofi Improvements relevant to products (excluding Technical Information which is exclusively relevant to Products) outside Diabetes in the Territory and that has not previously been disclosed to Ascendis. For clarity, nothing in this Agreement shall oblige Sanofi to supply to Ascendis the registration file of any Product save to the extent that Technical Information is relevant for the general use of the Technology Platform.
- 3.6 Ascendis will, through the appropriate mechanisms, use Diligent Efforts to maintain existing employment of certain key employees identified by Sanofi as holding that Technical Information necessary for the performance of the Development Plan and for the exercise of the rights granted to Sanofi to the Technology Platform.

4. **Development**

- 4.1 Ascendis shall perform and complete, or cause the performance and completion, as the case may be, of the Development Plan activities set forth in schedule 4 (“Ascendis Development Activities”) and deliver to Sanofi [***] arising therefrom within [***] following completion of the relevant studies as they are described in the Development Plan. As a condition to Sanofi making the payment of any of the three instalments referred to under Clause 7.1(D), the Ascendis Development Activities will be conducted under the effective supervision of the Business Team. Any results of the Ascendis Development Activities shall be considered as Joint Improvements licensed to Sanofi under Clause 2.3.

4.2 Joint Development Committee.

- (A) Formation. Promptly after the Effective Date, the Parties will form a Joint Development Committee (the “JDC”) comprised of Ascendis’ [***] and of [***] of Sanofi. One representative of Sanofi-Aventis at the JDC will be selected to act as the chairperson of the JDC. The JDC will meet at least [***] times per year during the term of the Development Plan. Such meetings may be conducted by videoconference, teleconference or in person, as agreed by the Parties. The JDC will agree upon the time and location of the meetings. The chairperson, or his or her designee, will circulate an agenda for each meeting approximately one week before the date scheduled for the meeting, and will include all matters requested to be included on such agenda by either Party. The chairperson, or his or her designee, will take complete and accurate minutes of all discussions occurring at the JDC meetings and all matters decided upon at the meetings except that matters reflecting legal advice of counsel (including for clarity patent counsel) will not be included in such minutes. A copy of the draft minutes of each meeting will be provided to each Party by the chairperson, or his or her designee, after each meeting, and such minutes will be reviewed by the JDC members, any needed changes discussed and final minutes agreed to and provided to each Party within thirty (30) days after each meeting unless otherwise agreed. A reasonable number of additional representatives of a Party may attend meetings of the JDC in a non-voting capacity. Each Party is responsible for their travel costs and expenses associated with attending meetings.

- (B) JDC Functions and Powers. The responsibilities of the JDC will be as follows:
- (1) encouraging and facilitating communication between the Parties with respect to the development of Products;
 - (2) reviewing the Development Plan,
 - (3) monitoring the progress of the development of Products and each Party's diligence in carrying out its responsibilities there under; and
 - (4) carrying out the other duties and responsibilities described for it in this Agreement.
- (C) JDC Decision Making. All decisions of the JDC will be made by unanimous vote, with each member having one vote. If after reasonable discussion and consideration of each of the Parties' views on a particular matter before the JDC, the JDC is unable to reach a decision by unanimous vote on that matter, then [***]; provided, however, that in no event shall [***] in a manner that (a) materially impairs or is reasonably likely to impair any rights or assets [***], or (b) results or is reasonably likely to result in (i) an increase in the scope of the [***] agreed by the Parties resulting in [***] or (ii) an [***]. The JDC shall not have any authority other than that expressly set forth above and, specifically, shall have no authority (x) to amend or interpret this Agreement, (y) to determine whether or not a Party has met its diligence or other obligations under the Agreement, or (z) to determine whether or not a breach of this Agreement has occurred.
- (D) Termination of JDC. The JDC shall terminate as of the earlier of (i) the acknowledgement by Sanofi that Ascendis has completed the Ascendis Development Activities, or (ii) the end of the [***] period of time following the Effective Date.

- 4.3 Except for the specific work to be performed by Ascendis in the Development Plan, Sanofi shall assume and have the sole responsibility for all development (including associated costs) of Product in the Territory in accordance with the provisions of this Agreement.
- 4.4 Sanofi reserves the right to approve (such approval not be unreasonable withheld) the appointment by Ascendis of any service providers intended to perform part of Ascendis' Development Plan activities on behalf of Ascendis.
- 4.5 As part of the Technical Information to be provided by Ascendis hereunder, Ascendis shall promptly provide to Sanofi all information (including copies, where applicable) of any current or future contracts between Ascendis or its Affiliates and any Independent Third Party suppliers or vendors that materially relate to the Development Plan or to the Products. At Sanofi's request, Ascendis shall use commercially reasonable efforts to assign or cause to be assigned (subject to assumption by Sanofi of the obligations) such agreements to Sanofi, to the extent that (i) such agreements relate solely to the development, manufacture and/or supply of Products and (ii) such assignment is permitted in accordance with the terms and conditions of such agreements or with the consent of the counterparty, or Ascendis shall reasonably cooperate to assist Sanofi in obtaining the benefit of such agreements.

- 4.6 Ascendis will cooperate with Sanofi-Aventis to provide such reasonable technical assistance as may be necessary in connection with the transfer to Sanofi-Aventis of the development, manufacture and production of Product as is consistent with the capacity and the capabilities of Ascendis. As part of such assistance, Ascendis will use commercially reasonable efforts to furnish, at Sanofi-Aventis' reasonable request, a representative to attend drug regulatory meetings regarding Product and/ or participate in activities related to such regulatory meetings.
- 4.7 The parties shall enter into good faith negotiations to agree a quality agreement within [***] of the Effective Date.
- 4.8 Sanofi undertakes to use Diligent Efforts to develop the First Product and the Second Product (as defined in Clause 7.1(C)) and to reach the milestones set forth in Clause 7.1(C)(1) to Clause 7.1(C)(8) inclusive, in the Territory. For the avoidance of doubt, after Sanofi has made all the milestone payments set forth in Clause 7.1(C)(1) to Clause 7.1(C)(8) inclusive, the obligations set forth in this Clause 4.8 shall be satisfied and have no further force or effect. Sanofi shall conduct all development of the Product in compliance with current Good Laboratory Practice, Good Clinical Practice and Good Manufacturing Practice (where applicable).
- 4.9 Sanofi shall keep Ascendis regularly and fully informed of the progress of development of Product as set forth in Clause 7.1(C).
5. **Manufacturing and Commercialisation**
- 5.1 Sanofi shall be solely responsible for all Manufacturing and commercialisation activities relating to Product in the Territory.
- 5.2 Sanofi shall, and it shall procure that its Affiliates and any Sub-Licensees shall:
- (A) ensure that any packaging together with any inserts or material relating to the sale of Product are, marked, where practicable, with all relevant patent numbers of Patents and with a clear and prominent statement that the Product incorporates the technology conceived by Ascendis; and
 - (B) conduct all packaging and distribution in accordance with current Good Manufacturing Practice.
- 5.3 Sanofi undertakes to use Diligent Efforts to commercialise [***] in [***] and to reach the milestones set forth in Clause 7.1(C)(9) and Clause 7.1(C)(10). For the avoidance of doubt, after Sanofi has made all the milestone payments set forth in Clause 7.1(C)(9) and Clause 7.1(C)(10), the obligations set forth in this Clause 5.3 shall be satisfied and have no further force or effect.
6. **Regulatory**
- 6.1 Sanofi shall have the sole responsibility for obtaining and maintaining all Regulatory Approvals (including associated costs) for Product from Regulatory Authorities in each of the countries in the Territory.

6.2 Sanofi undertakes to comply, and to procure that its Sub-Licensees comply, with all requirements of Regulatory Authorities and/or applicable law, regulation and guidance.

7. Payments

7.1 Sanofi shall make the following non-refundable purchase, licence fee and milestone payments to Ascendis:

- (A) Purchase price. In consideration of the purchase of the Product Patents, Sanofi shall pay Ascendis a non-refundable (subject to Section 19.4 hereunder), non-creditable one-time purchase price in the amount of [***]. On or promptly after the Effective Date, Ascendis shall submit an invoice to Sanofi for such amount, and Sanofi shall pay such invoice within [***] after receipt of such invoice.
- (B) Licence Fee. In consideration of the rights and licences granted to Sanofi under the Technology Platform Patents, and other licence rights granted to it under this Agreement, Sanofi shall pay Ascendis a non-refundable, non-creditable one-time licence fee in the amount of [***]. On or promptly after the Effective Date, Ascendis shall submit an invoice to Sanofi for such amount, and Sanofi shall pay such invoice within [***] after receipt of such invoice.
- (C) Development and Sale Milestones. Sanofi shall pay Ascendis the following one-time milestone payments upon the first occurrence of each event set forth below achieved by Sanofi, its Affiliates, its Sub-Licensees or their distributors:

Milestone N°	Description	Amount (€)
1	[***]	[***]
2	[***]	[***]
3	[***]	[***]
4	[***]	[***]
5	[***]	[***]
6	[***]	[***]
7	[***]	[***]
8	[***]	[***]
9	[***]	[***]
10	[***]	[***]

Should a First or Second Product [***] [***], the sum of the milestone payments [***] (i.e. [***]) would be paid to Ascendis upon [***] for such Product.

In the event that the development of a First Product or a Second Product is suspended or discontinued (each a “Suspended Product”), and another Product is developed instead of the Suspended Product (each a “Replacement Product”), any payments actually paid under Clause 7.1(C)(1) to Clause 7.1(C)(8), inclusive, in respect of the Suspended Product shall not be due in respect of the Replacement Product but any payments not paid in respect of the Suspended Product shall be payable on the Replacement Product achieving the relevant milestone described in Clause 7.1(C)(1) to Clause 7.1(C)(8), inclusive. For clarity, Sanofi may not be obliged to pay to Ascendis more than [***] under this Clause 7.1(C).

For the avoidance of doubt, in the event that the milestones described in Clause 7.1(C)(9) and Clause 7.1(C)(10) are achieved in the same calendar year, both payments shall be paid by Sanofi to Ascendis.

Sanofi shall provide Ascendis with written notice of the achievement of any of the foregoing events within [***] thereafter. Upon receipt of such notice, Ascendis shall submit an invoice to Sanofi for the amount of such milestone payment, and Sanofi shall pay the respective payment for such event within [***] after receipt of such invoice from Ascendis. For the avoidance of doubt, after Sanofi has paid any of the foregoing payments, Sanofi shall have no further obligation to make such payment again.

(D) Funding of Ascendis Development Activities. Subject to the condition referred to under Clause 4.1, Sanofi will fund Ascendis Development Plan Expenses for activities to be performed by Ascendis under the Development Plan, by paying the following three yearly instalments:

- Year 1: [***]

- Year 2: [***]

- Year 3: [***]

The first yearly instalment shall be paid to Ascendis within [***] of the Effective Date or [***] after the Parties agree on the Development Plan (to be attached as schedule 4), whichever is earlier, subject to receipt by Sanofi of the corresponding invoice to be issued by Ascendis.

The second yearly instalment shall be paid to Ascendis [***], subject to receipt by Sanofi of the corresponding invoice to be issued by Ascendis.

The third yearly instalment shall be paid to Ascendis [***], subject to receipt by Sanofi of the corresponding invoice to be issued by Ascendis.

Such funding will cover [***] Ascendis Development Plan Expenses as described in the initial Development Plan. The Parties will agree in writing on the payment of [***] Ascendis Development Expenses, before they are effectively incurred by Ascendis. For clarity, Ascendis shall not be obliged to incur costs in respect of the Development Plan in any relevant year which are in excess [***] [***] in accordance with this Clause 7.1(D).

- 7.2 All payments due under this Agreement shall be made in Euros to the credit of a bank account to be designated in writing by Ascendis. Conversion into Euros of any amounts under this Agreement will be made in a manner consistent with Sanofi's normal practices used to prepare its audited financial statements for internal and external reporting purposes, which uses a widely accepted source of published exchange rates.
- 7.3 Subject to Clause 7.4, Ascendis shall bear any and all taxes levied on account of any payment received under this Agreement. In the event that Sanofi is required, under applicable laws, to withhold any deduction or tax from any payment due to Ascendis under this Agreement, such amount shall be deducted from the payment to be made by Sanofi, paid to the proper taxing authority, provided that Sanofi shall take reasonable and lawful actions to avoid and minimize such withholding and promptly notify Ascendis so that Ascendis may take lawful actions to avoid and minimize such withholding. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.
- 7.4 All sums payable by Sanofi under or pursuant to this Agreement are exclusive of VAT (if any). Accordingly, where any taxable supply for VAT purposes is made under or in connection with this Agreement by Ascendis to Sanofi, Sanofi shall, in addition to any payment required for that supply, pay to Ascendis such VAT as is chargeable in respect of the supply at the same time as payment is due. Sanofi shall provide to Ascendis, prior to the due date for payment or the raising of any invoice (whichever is the earlier), details of Sanofi's own VAT registration number. Ascendis shall provide Sanofi with a valid VAT invoice in respect of any payment of VAT.
- 7.5 Where any fees, milestones or other sums payable by Sanofi to Ascendis hereunder remain unpaid after the date on which they became due, Sanofi shall pay to Ascendis interest calculated from the date upon which the sums became due until payment thereof at the base lending rate of the European Central Bank ruling at the date the sums became due plus [***].
- 7.6 Notwithstanding anything to the contrary contained herein, upon payment in full of the last milestone payment set forth in Clause 7.1(C) by Sanofi to Ascendis, the licences granted pursuant to Clause 2.3 shall be deemed to be fully paid-up, royalty-free, perpetual and irrevocable.

8. Records and Auditing

- 8.1 Each Party shall, and the Licensee shall procure that its Affiliates and Sub-Licensees shall, maintain complete and accurate books, records and accounts used for the determination of any payment obligations under this Agreement, which books, records and accounts will be retained by such Party until [***] after the end of the period to which such books, records and accounts pertain.
- 8.2 Each Party will have the right to have an independent certified public accounting firm of internationally recognized standing, reasonably acceptable to the other Party, have access during normal business hours, and upon [***] prior written notice, to such of the records of the other Party and its Affiliates as may be reasonably necessary to verify the accuracy of any payment made or received during the [***] prior to the date of such request; provided, however, that no Party will have the right to conduct more than one such audit in any [***] period. The accounting firm will disclose to the Parties only whether the data reported by the audited Party are correct or incorrect and the specific details concerning any discrepancies. The auditing Party will bear all costs of such audit, unless the audit reveals a discrepancy in the auditing Party's favour of more than [***], in which case the audited Party will bear the cost of the audit. The results of such accounting firm will be final, absent manifest error.

8.3 If, based on the results of any audit, additional payments are owed Ascendis under this Agreement, then Sanofi will make such additional payments promptly after the accounting firm's written report is delivered to both Parties. If, based on the results of any audit, any payments made by Sanofi to Ascendis exceeded the amounts due and payable under this Agreement, then Ascendis will return such excess to Sanofi promptly after the accounting firm's written report is delivered to both Parties.

9. **Pharmacovigilance**

9.1 Upon execution of this Agreement, the Parties shall promptly, and in any event before Sanofi starts any clinical development activities, agree on the terms of a safety data exchange agreement (the "**SDEA**") for the collection, reporting and exchange of safety information. The Parties shall immediately implement such SDEA and shall provide each other on a regular basis with any information which has become available to them and which is relevant to the safe use of Product (or of product, where applicable). Such procedures shall also relate to Sanofi's Affiliates and Sub-Licensees.

9.2 Each Party shall notify the other of a "serious adverse experience" or "unexpected adverse experience" (as defined below) and will manage the same in accordance with the terms of the SDEA. For the purposes of this Clause 9.2, "serious adverse experience" shall mean any adverse event associated with the use of Product in humans (whether or not considered drug-related) that gives rise to one or more of the following: death, threat to life, new or prolonged in-patient hospitalisation, permanent or significant disability or incapacitation, overdose, congenital abnormality, or serious laboratory abnormality which is thought by the reporting physician to be serious or associated with relevant clinical signs or symptoms. An "unexpected adverse experience" shall mean any adverse event that is not identified in nature, severity, or frequency in the then current investigation brochure for Product (or of product, where applicable) or approved prescribing information.

10. **Confidentiality**

10.1 Sanofi agrees to keep secret Ascendis' confidential Technical Information, Ascendis Improvements and all other confidential information that it may obtain from Ascendis, its Affiliates or licensees in the course of this Agreement, to use the same exclusively as permitted under this Agreement, and to disclose the same only to those of its employees, contractors, consultants, Affiliates and Sub-Licensees to whom and to the extent that such disclosure is reasonably necessary in accordance with this Agreement.

10.2 Ascendis agrees to keep secret Sanofi's confidential Technical Information, Sanofi's Improvements and all other confidential information that it may obtain from Sanofi, its Affiliates and Sub-Licensees in the course of this Agreement, to use the same exclusively as permitted under this Agreement, and to disclose the same only to those of its employees, contractors, Affiliates and Sub-Licensees to whom and to the extent that such disclosure is reasonably necessary in accordance with this Agreement.

10.3 The foregoing obligations of Clauses 10.1 and 10.2 shall not apply to Technical Information or other information which:

(A) prior to receipt thereof from one Party was in the possession of the recipient Party and at its free disposal;

- (B) is subsequently disclosed to the recipient Party without any obligations of confidence by an Independent Third Party who has not derived it directly or indirectly from the disclosing Party;
- (C) is or becomes generally available to the public through no act or default of the recipient Party or its agents, contractors or employees;
- (D) is independently developed by the receiving Party without the benefit of any disclosure hereunder, as demonstrated by documented evidence prepared contemporaneously with such independent development; or
- (E) is required to be disclosed by law, regulation or action of any governmental agency or authority.

10.4 Each Party shall procure that all its employees, contractors, Affiliates and Sub-Licensees who have access to any information of the other to which the obligations of Clauses 10.1 or 10.2 as the case may be apply, shall be made aware of, subject to, and comply with those obligations. During the term of this Agreement, each Party shall [***] protect and prevent the misappropriation of Technical Information by any of its employees or contractors or any Independent Third Party, including where appropriate by initiating legal action against any such employee, contractor or Independent Third Party, as applicable.

10.5 Each Party ("Publishing Party") shall submit to the other Party manuscripts, including abstracts, and texts of poster presentations and other external presentations containing confidential Technical Information or other information at least [***] prior to presentation or submission for publication for purposes of allowing the other Party to comment on the manuscript or text; provided that the other Party may require the Publishing Party, by giving notice in writing to the Publishing Party within [***] of the receipt of such manuscript, abstract, text or other external presentations from the Publishing Party to stop submission for publication or presentation of such manuscript, abstract, text or other external presentation if, in the reasonable opinion of the other Party such delay is necessary in order to permit the filing of any patent application or to protect commercially sensitive data in respect of some or all of the other Party's confidential information contained in such manuscript, abstract, text or other external presentation.

10.6 Promptly upon execution of this Agreement, each Party may issue an initial press release disclosing the execution of this Agreement and its contents, subject to the prior written consent of the other Party (which consent shall not be unreasonably withheld or delayed) to the contents of such press release. Neither Party shall make any other press releases or other public announcement(s) or disclosures to any third party relating to this Agreement, or any term hereof, without the prior written consent of the other Party (which consent shall not be unreasonably withheld or delayed), except where such disclosure is required by applicable law, in which case the disclosing party shall, to the extent permitted by applicable law, provide copies of the disclosure reasonably in advance of such disclosure for the non-disclosing Party's prior review and comment.

11. Prosecution, Maintenance and Defence

11.1 Sanofi shall be responsible for filing, prosecuting and defending the Product Patents and any new patent Covering a Product, a Sanofi Improvement or a Joint Improvement. Ascendis shall, upon request by Sanofi and at the expenses of Sanofi, provide reasonable assistance to Sanofi with regard to such filing, prosecution and defence activities.

- 11.2 Subject to clause 11.3, Ascendis shall be responsible for filing, prosecuting, maintaining and defending the Technology Platform Patents and any patents Covering Ascendis Improvements. Ascendis will provide Sanofi with drafts of all such proposed filings and correspondence (including without limitation the initial application as well as any material correspondence received from any Independent Third Parties or Intellectual Property Office related to any filings) which are relevant to Diabetes in the Territory. Sanofi shall have [***] to review and comment on such filings and correspondence, unless the date of receipt by Ascendis of such filings and correspondence and the official deadline set by such Intellectual Property Office is such that Sanofi's period of review and comment should be shorter, in which case Ascendis shall provide such filings and correspondence as soon as practicable and inform Sanofi of such shorter period. Ascendis shall consider all of Sanofi's reasonable suggestions, recommendations and instructions concerning the preparation, filing, prosecution, defence and maintenance of the Technology Platform Patents (including without limitation any suggestion or recommendation to alter or limit the scope, content and/or claims of any such application) and, to the extent otherwise practicable, shall undertake the preparation, filing, prosecution and defence of the Technology Platform Patents in a way that will not be detrimental to the research, development or commercialization of any Products. Ascendis agrees to file the Technology Platform Patents and any new patent Covering the Ascendis Improvements thereto in each of the countries listed on schedule 7 to the extent practicable. Ascendis shall not abandon or allow to lapse any Technology Platform Patent or any new patents Covering the Technology Platform or any Ascendis Improvements in Diabetes in any other country of the Territory without first giving Sanofi the opportunity to [***], provided that maintenance of such patent will not in Ascendis' reasonable opinion impair Ascendis' intellectual property protection in any respect for the Technology Platform and any products (other than Glp-1 Product, Glucagon Product, Insulin Product and any combination of Glp-1 Product, Glucagon Product and/or Insulin Product).
- 11.3 Ascendis shall bear the costs of filing, prosecuting, maintaining and defending the Technology Platform Patents. With effect from the Effective Date, Sanofi shall be responsible for the costs of filing, prosecuting, maintaining and defending the Product Patents and any new patent Covering a Product, a Sanofi Improvement or a Joint Improvement.
- 11.4 Each Party agrees that it will conduct its filing, prosecution, maintenance and defence activities in relation to its patent applications and patents in a manner that is not detrimental to the other Party's Patents and/or to any patent applications filed by or granted to such other Party to Cover its Improvements.

12. Improvements

- 12.1 Subject to the provisions of Clause 12.2, Ascendis shall own all right, title and interest in and to any and all Ascendis Improvements. Ascendis shall [***] be responsible for filing, prosecuting, maintaining and defending any patent Covering Ascendis Improvements.
- 12.2 Any Ascendis Improvement which is necessary or useful for the development, manufacture or commercialization of a Product shall be included in the licences granted to Sanofi under Clause 2.3.
- 12.3 Sanofi shall own all right, title and interest in and to any and all Sanofi Improvements. Sanofi shall [***] be responsible for filing, prosecuting, maintaining and defending any patent claiming Sanofi Improvements. If Sanofi does not wish to maintain or defend any such patent or if Sanofi wishes to abandon any such patent or allow any such patent to lapse, and provided that maintenance of such patent will not in Sanofi's reasonable opinion impair Sanofi's intellectual property protection in any respect of Product or Sanofi Improvement, Sanofi shall first offer in writing to Ascendis an opportunity to acquire such patent(s) with the right to use such patent(s) as it wishes, without compensation to Sanofi.

12.4 Any Sanofi Improvement which is necessary or useful for the development, manufacture or commercialization of a product (excluding Product) by Ascendis or relates to the Technology Platform shall be included in the Technical Information and shall be included in the licence granted to Ascendis under Clause 2.2.

13. **Infringement**

13.1 By an Independent Third Party

- (A) In the event of Sanofi or Ascendis becoming aware of any suspected infringement or any unauthorised use by an Independent Third Party of any of the Patents, Ascendis Improvements, Sanofi Improvements, Joint Improvements or Technical Information in the Territory, the Party becoming aware of the same shall notify the other Party.
- (B) Where such suspected infringement or unauthorised use (i) is outside [***], Ascendis shall [***] have the exclusive right to take or threaten any legal action that it deems appropriate to halt such suspected infringement and to retain any amounts recovered in respect of such suspected infringement or unauthorised use.
- (C) Where such suspected infringement relates to any [***] or to any [***], Sanofi shall [***] have the exclusive right to take or threaten any legal action that it deems appropriate to halt such suspected infringement and to retain any amounts recovered in respect of such suspected infringement or unauthorised use.
- (D) Where such suspected infringement is within [***] but does not relate to any [***] or to any [***]:
 - (1) the Parties shall consult with each other with reasonable diligence in order to consider whether legal action should be taken or threatened concerning such suspected infringement or unauthorised use;
 - (2) if the Parties agree that legal action should be taken or threatened, then they shall share [***] the costs of threatening or taking such legal action and in any amounts recovered as a result of the taking of such action unless the Parties otherwise agree in writing. In such circumstances, Sanofi shall have conduct of the action but shall consult Ascendis in good faith with regard to all significant decisions;
 - (3) if Sanofi wishes to take or threaten legal action but Ascendis does not, then Sanofi may request Ascendis to lend its name where necessary or desirable to proceedings relating to such action and provide reasonable assistance in such proceedings and Ascendis will do so subject to Sanofi [***] [***]. In such circumstances, Sanofi shall have conduct of the action but shall consult Ascendis in good faith with regard to all significant decisions. In addition, Sanofi shall be [***]; and

- (4) in any event, neither Party shall take any steps to settle or compromise such legal action or to reject the same without the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed).

13.2 Against an Independent Third Party

- (A) In the event that the development or commercialisation of Product (or of products, where applicable) results in action by an Independent Third Party against a Party (or its Affiliates or Sub-Licensees) for infringement or unauthorised use of intellectual property or confidential information anywhere in the Territory, such Party shall promptly notify the other Party in writing.
- (B) Each Party (or its Affiliates or Sub-Licensees) against whom such action is brought shall (i) have the right but not the obligation to defend such action, (ii) have the right to be represented by separate legal advisors, (iii) keep the other Party informed of, and assist and co-operate with the other Party in, any such action and (iv) bear its own costs.

14. **Warranties**

14.1 Each Party warrants to the other Party that:

- (A) it is free to enter into this Agreement and to carry out its obligations hereunder without violating any obligation owed by it or any of its Affiliates to any Independent Third Party;
- (B) it shall not, during the existence of this Agreement, enter into any assignments, licences, obligations, charges or assignments, either written, oral or implied, which are or shall be inconsistent with this Agreement; and
- (C) it has obtained all necessary corporate approvals to enter into and execute this Agreement.

14.2 Ascendis represents and warrants to Sanofi, as of the Effective Date:

- (A) Ascendis has the right to grant the licence granted to Sanofi on the terms set forth in Clause 2.3;
- (B) **schedule** 1 accurately identifies all Patents owned by or licensed to Ascendis as of the Effective Date that claim a Product or its manufacture or use;
- (C) All application and renewal fees required for the maintenance of the Patents have been duly and timely paid;
- (D) There is no pending litigation or claim served against Ascendis or any Affiliate of Ascendis that (i) alleges that any of Ascendis' or any of its Affiliates' activities relating to the Products or the Platform Technology have violated, or by developing Products would violate, any of the intellectual property rights of any third party (nor has it received at its corporate offices any written communication addressed to senior management threatening such litigation), or (ii) seeks to invalidate any of the Patents. During the term of this Agreement, Ascendis shall promptly notify Sanofi in writing upon learning of any such threatened claim or litigation;

- (E) Ascendis owns all right, title and interest in and to, or holds a licence to, the Patents, free and clear of all encumbrances, security interests, options and licences;
- (F) Ascendis or its Affiliates (i) have obtained the assignment of all interests and all rights of its employees with respect to the Patents, and (ii) have taken reasonable measures to protect the confidentiality of those items in the Ascendis Technical Information that are confidential;
- (G) So far as Ascendis is aware, there is no use, infringement or misappropriation of the Patents or the Ascendis Technical Information, in derogation of the rights granted to Sanofi in this Agreement;
- (H) All third party patents actually known to Ascendis that Ascendis believes would be infringed by the development or commercialization of the Product by Sanofi in accordance with this Agreement are identified in the freedom to operate searches provided by Ascendis to Sanofi on or prior to the Effective Date;
- (I) So far as Ascendis is aware, there are no investigations, inquiries, actions or other proceedings pending before any Regulatory Authority or other government agency with respect to any Product, and Ascendis has not received at its corporate offices any written notice addressed to senior management threatening any such investigation, inquiry, action or other proceeding. During the term of this Agreement, Ascendis shall promptly notify Sanofi in writing upon learning of any such actual or threatened investigation, inquiry, action or proceeding;
- (J) schedule 5 accurately identifies all licences granted to Ascendis by any Independent Third Parties with respect to the Products, their formulation, Manufacture or use, and so far as Ascendis is aware, Ascendis is not in breach or default under any such licence and has not received from any licensor any written notice of breach or default;
- (K) All employees of Ascendis and of its Affiliates (including without limitation each member of the Business Team) are individually bound to Ascendis or its Affiliates by written confidentiality undertakings during the term of their employment with Ascendis or its Affiliates;
- (L) The employees listed in Part II of schedule 6 are individually bound to Ascendis by non-compete undertakings while they remain shareholders in Ascendis; and
- (M) Ascendis has disclosed in writing and/or made available to Sanofi for its review, all filings or material correspondence between Ascendis or its Affiliates and Regulatory Authorities and all study reports that are related to any Glp-1 Product, Glucagon Product or any Insulin Product or any combination of Glp-1 Product, Glucagon Product and/or Insulin Product.

14.3 To the fullest extent permitted by law, Ascendis excludes all other warranties, express or implied, in respect of the Patents, Technical Information and Product, including without limitation any warranties in respect of merchantability, fitness for purpose, satisfactory quality, completeness or accuracy.

14.4 Sanofi warrants that it has the commercial, technical and financial resources and expertise available, and intends to use them, to develop Product in the Territory as contemplated in Clause 4.3 of this Agreement.

15. Indemnification

15.1 Ascendis shall indemnify, defend and hold Sanofi and its Affiliates, and their respective directors, officers, employees and agents (each a "Sanofi Indemnatee") from and against all losses, liabilities, damages, settlements, claims, actions, suits, penalties, fines, costs or expenses (including reasonable attorney's fees) to the extent relating to an Independent Third Party claim, action or demand (each a "Loss") arising out of or resulting from the negligence, recklessness, intentional acts or omissions in relation to this Agreement, or the performance of the Development Plan Activities, or the manufacture, supply, marketing, sale or use of products, or infringement of intellectual property or misappropriation or unauthorised disclosure of confidential information by Ascendis or its Affiliates and their respective directors, officers, employees and agents, except to the extent such Independent Third Party claim, action or demand arose or resulted from the negligence, recklessness, intentional acts or omissions of Sanofi or its Affiliates and their respective directors, officers, employees and agents in relation to this Agreement.

15.2 Except as provided in Clause 15.1 above, Sanofi shall indemnify, defend and hold Ascendis, its Affiliates, and their respective directors, officers, employees and agents (each a "Ascendis Indemnatee") from and against all losses, liabilities, damages, settlements, claims, actions, suits, penalties, fines, costs or expenses (including reasonable attorney's fees) to the extent relating to an Independent Third Party claim, action or demand (each a "Loss") arising out of or resulting from the negligence, recklessness, intentional acts or omissions in relation to this Agreement, or the performance of the Development Plan Activities, or the manufacture, supply, marketing, sale or use of product, or infringement of intellectual property or misappropriation or unauthorised disclosure of confidential information by Sanofi or its Affiliates or Sub-licensees, and their respective directors, officers, employees and agents, except to the extent such Independent Third Party claim, action or demand arose or resulted from the negligence, recklessness, intentional acts or omissions of Ascendis, its Affiliates or licensees (other than Sanofi) and their respective directors, officers, employees and agents in relation to this Agreement.

15.3 In the event that a Sanofi Indemnatee or an Ascendis Indemnatee, as applicable (hereinafter an "Indemnified Party") seeks indemnification under this Clause 15, such Indemnified Party shall: (i) give prompt notice to the indemnifying Party of any such claim, action or demand; (ii) permit the indemnifying Party to assume direction and control of the defence of such claim, action or demand (including decisions regarding its settlement or other disposition, which may be made in the indemnifying Party's sole discretion except as otherwise provided herein); (iii) assist the indemnifying Party at the indemnifying Party's expense in defending such claim, action or demand; and (iv) not compromise or settle such claim, action or demand without the indemnifying Party's prior written consent, which shall not be unreasonably withheld or delayed. The Indemnified Party may participate in the defence of such claim, action or demand through counsel of its choice, but the reasonable cost of such counsel shall be borne solely by the Indemnified Party. Except with the approval of the Indemnified Party, which approval shall not be unreasonably withheld or delayed, the indemnifying Party shall not enter into any settlement which (i) would result in injunctive or other relief being imposed against an Indemnified Party; or (ii) does not include as an unconditional term thereof the giving by the claimant to all applicable Indemnified Parties of a release from all liability in respect to such claim or litigation.

16. Limitation of Liability

- 16.1 Subject to Clause 16.2, neither of the Parties nor any of their Affiliates shall be liable to each other under any contract, negligence, strict liability or other legal or equitable theory for indirect, incidental, special, punitive, exemplary or consequential damages arising out of or resulting from this Agreement. The foregoing shall not limit the obligations of either Party from and against Independent Third Party Claims under Clauses 15.1 or 15.2 to the extent that such Independent Third Party has been awarded such damages.
- 16.2 Neither Party limits or excludes its liability for fraud, fraudulent concealment or fraudulent misrepresentation, nor for death or personal injury arising from its negligence.

17. Term and Survival

- 17.1 This Agreement shall commence with effect from the Effective Date and shall continue until expiration of the Patents unless earlier terminated pursuant to Clause 18.
- 17.2 On the expiration or termination of this Agreement each Party shall continue to be bound by the Clauses 2.2 (licence to Ascendis, only in respect of Sanofi Improvements and Joint Improvements that are in existence prior to expiration or termination), 2.8 (immunity from suit), 10 (confidentiality), 15 (indemnification), 16 (limitation of liability), 17 (term and survival), 19 (effect of termination) and 20 (miscellaneous).

18. Termination

- 18.1 In the event that Sanofi fails to remit any undisputed sum that it is obligated to pay to Ascendis under Clause 7 and such failure is not made good within thirty (30) Business Days after receipt by Sanofi of a written notice thereof given by Ascendis, then Ascendis may by written notice terminate this Agreement forthwith. The preceding sentence of this Clause 18.1 shall not apply to any failure of Sanofi to remit the sums which it is obligated to pay to Ascendis under Clauses 7.1(A) and 7.1(B), and in the event that such sums are not paid to Ascendis within the time periods set out in Clauses 7.1(A) and 7.1(B), Ascendis shall have the right to terminate this Agreement forthwith on written notice to Sanofi.
- 18.2 In the event that either Party commits a material breach of any of the other terms of this Agreement on its part to be performed or observed, the other Party shall have the right to terminate this Agreement by giving sixty (60) Business Days' written notice to the defaulting Party; provided however that in the case of a material breach capable of being made good, if the defaulting Party shall make good the said material breach within sixty (60) Business Days after the notice shall have been given, then the notice shall not be effective.
- 18.3 Sanofi may at any time, upon ninety (90) Business Days' written notice, terminate this Agreement in its entirety, for convenience.
- 18.4 If at any time during this Agreement, any Party (the "Challenging Party") institutes against the other Party a lawsuit or proceeding in a court or before another tribunal of competent jurisdiction in the nature of a declaratory judgment action of non-infringement, invalidity or unenforceability with respect to any patent licensed to the Challenging Party hereunder, then the other Party shall be entitled to terminate this Agreement forthwith on written notice to the Challenging Party.

19. Effect of Termination

19.1 The termination of this Agreement shall be without prejudice to:

- (A) the obligation of Sanofi to pay to Ascendis all milestones achieved prior to termination and other sums accrued, due and payable under Clause 7; and
- (B) any right of, or remedy available to, either Party against the other in respect of anything done or omitted hereunder prior to such termination.

19.2 If this Agreement is terminated by Ascendis pursuant to Clause 18.1, 18.2 or 18.4, or by Sanofi in its entirety pursuant to Clause 18.3:

- (A) Sanofi shall promptly return, furnish, transfer and/or assign to Ascendis all written Technical Information relating to the Technology Platform which at the date of termination is confidential, without compensation to Sanofi. For the avoidance of doubt, Ascendis, its Affiliates, licensees and Sub-Licensees shall be entitled to use all such Technical Information and Sanofi, shall, and shall procure that its Affiliates and Sub-Licensees shall immediately cease to use and thereafter refrain from using such confidential Technical Information.
- (B) All rights of Sanofi hereunder [***] and all licences granted to Sanofi hereunder shall forthwith cease and terminate;
- (C) Sanofi shall and shall procure that its Affiliates and Sub-Licensees shall, cooperate and provide reasonable assistance to Ascendis in obtaining the transfer or grant of any Regulatory Approvals in the Territory for any Product (other than (i) Glp-1 Product, Glucagon Product, Insulin Product and any combination of Glp-1 Product, Glucagon Product and/or Insulin Product) and (ii) any Product Covered by the Product Patents) to Ascendis or its nominee and shall ensure that Ascendis is supplied with copies of all relevant reports submitted to the Regulatory Authorities for the purpose of obtaining the transfer or grant of such Regulatory Approvals in the Territory with regard to any such Product in Diabetes, Diabetes Related Metabolic Disorders and/or Obesity;
- (D) the licences granted by Sanofi to Ascendis pursuant to Clause 2.2 shall survive termination and continue in full force and effect; and
- (E) Sanofi shall pay to Ascendis all justified and documented external costs and expenses that Ascendis and/or its Affiliates incur in the winding down of activities under the Development Plan.
- (F) Subject to Clause 19.4, Ascendis may, at its discretion, [***].

19.3 In the case of termination by Sanofi pursuant to Clause 18.2:

- (A) all rights of Ascendis hereunder and all licences granted to Ascendis hereunder shall forthwith cease and terminate; and
- (B) the licence granted by Ascendis to Sanofi pursuant to Clause 2.3 shall survive termination and shall remain in full force and effect.

19.4 In case of termination by Sanofi pursuant to Clause 18.3 prior to IND Approval of any Product, and if Ascendis notifies Sanofi in writing that it wants to own the Product Patents, Sanofi shall promptly return, furnish, transfer and/or assign to Ascendis the Product Patents upon payment by Ascendis to Sanofi of [***].

20. Miscellaneous

20.1 Further Assurances

At any time after the date hereof each of the Parties shall, at the request and cost of the other Party, execute or procure the execution of such documents and do or procure the doing of such acts and things as the Party so requiring may reasonably require for the purpose of giving to the Party so requiring the full benefit of all the provisions of this Agreement, subject to any express restrictions in this Agreement on the extent of either Party's obligations under this Agreement. This includes in particular (without prejudice to the generality of the foregoing) entry into forms of licence or other instruments confirming such rights for registration with appropriate Intellectual Property Offices, Regulatory Authorities and other authorities in the Territory.

20.2 Severability

In the event that any provision or any part of any provision contained in this Agreement is declared invalid or unenforceable by the judgment or decree by consent or otherwise of a Court of competent jurisdiction not subject to appeal, all other provisions or parts of provision contained in this Agreement shall remain in full force and effect and shall not be affected thereby for the term of this Agreement.

20.3 Assignments

Neither this Agreement nor any of the rights and obligations created herein is assignable or transferable (save for any sub-licence granted in accordance with Clauses 2.2, 2.3 and 2.5) by either Party without the prior written consent of the other, such consent not to be unreasonably withheld or delayed. Notwithstanding the preceding sentence:

- (A) subject to the provisions of Clause 2.7, Ascendis is entitled to assign this Agreement and/or any rights created herein to, subject to the assumption of the obligations herein by, any purchaser of the whole or a substantial part of the business of Ascendis. For the avoidance of doubt, the Parties agree that the Technology Platform constitutes a substantial part of the business of Ascendis.
- (B) Sanofi is entitled to assign this Agreement (but not part of this Agreement) to, subject to the assumption of the obligations herein by, any Affiliate or to any purchaser of the whole or a substantial part of the business of Sanofi, provided that such business includes [***].

20.4 Rights cumulative and other matters

- (A) The rights, powers, privileges and remedies provided in this Agreement are cumulative and are not exclusive of any rights, powers, privileges or remedies provided by law or otherwise.
- (B) No failure to exercise nor any delay in exercising by any Party to this Agreement of any right, power, privilege or remedy under this Agreement shall impair or operate as a waiver thereof in whole or in part.

- (C) No single or partial exercise of any right, power privilege or remedy under this Agreement shall prevent any further or other exercise thereof or the exercise of any other right, powers, privilege or remedy.

20.5 **Costs of Preparation**

The Parties hereto shall pay their own respective legal costs incurred in the preparation of this Agreement.

20.6 **Entire Agreement**

- (A) This Agreement, together with any documents referred to in it, constitutes the whole agreement between the Parties relating to its subject matter and supersedes and extinguishes any prior drafts, agreements, undertakings, representations, warranties and arrangements of any nature, whether in writing or oral, relating to such subject matter.
- (B) Each Party acknowledges that it has not been induced to enter into this Agreement by any representation or warranty other than those contained in this Agreement and, having negotiated and freely entered into this Agreement, agrees that it shall have no remedy in respect of any other such representation or warranty except in the case of fraud.
- (C) No variation of this Agreement shall be effective unless made in writing and signed by each of the Parties.

20.7 **Notices**

- (A) Any notice (which term shall in this Clause 20.7 includes any communication) required to be given under this Agreement or in connection with the matters contemplated by it shall, except where otherwise specifically provided, be in writing in the English language.
- (B) Any such notice shall be addressed as provided in Clause 20.7(C) and may be:
 - (1) personally delivered, in which case it shall be deemed to have been given upon delivery at the relevant address if it is delivered not later than 17.00 hours on a Business Day, or, if it is delivered later than 17.00 hours on a Business Day or at any time on a day which is not a Business Day, at 08.00 hours on the next Business Day; or
 - (2) sent by pre-paid airmail, or by air courier in which case it shall be deemed to have been given seven (7) Business Days after the date of posting in the case of airmail or two (2) Business Days after delivery to the courier, in the case of air courier; or
 - (3) sent by facsimile, in which case it shall be deemed to have been given when despatched, subject to confirmation of uninterrupted transmission by a transmission report, provided that any notice despatched by facsimile after 17.00 hours on any Business Day or at any time on a day which is not a Business Day shall be deemed to have been given at 08.00 on the next Business Day; or

- (4) sent by electronic mail, in which case, it shall be deemed to be given when received but subject to the same provisions regarding receipt after 17.00 hours as apply to notices sent by facsimile.
- (C) The addresses and other details of the Parties referred to in this Clause 20.7(C) are, subject to Clause 20.7(D):
- Ascendis' Address:
- Ascendis Pharma A/S
Tuborg Boulevard 12
DK-2900 Hellerup
Denmark
Fax no: +[***]
Attention: [***]
- Sanofi's Address:
- Sanofi-Aventis Deutschland GmbH
Industriepark Höchst
65926 Frankfurt am Main
Germany
Fax no: +[***]
Attention: [***]
- (D) Either Party to this Agreement may notify the other Party of any change to the address or any of the other details specified in Clause 20.7, provided that such notification shall only be effective on the date specified in such notice or five (5) Business Days after the notice is given, whichever is later.

20.8 Force Majeure

- (A) Neither Party to this Agreement shall be deemed to be in breach of this Agreement or otherwise liable to the other as a result of any delay or failure in the performance of its obligations under this Agreement if and to the extent that such delay or failure is caused by Force Majeure and the time for performance of the relevant obligation(s) shall be extended accordingly. The Party concerned shall promptly notify the other Party of the nature and effect of such event and both Parties shall where the same is practicable use Diligent Efforts to minimise such effect and to comply with the respective obligations herein contained as nearly as may be in their original form, provided that if the Force Majeure event continues for a period of [***] or more following notification, the Party not affected by the event may terminate this Agreement by giving not less than [***] prior notice to the other Party.
- (B) For the purposes of Clause 20.8, "**Force Majeure**" means any circumstances not within the reasonable control of the Party concerned including, without limitation (i) any strike, lockout or other industrial action, or any shortage of or difficulty in obtaining labour, fuel, raw materials or components; (ii) any destruction, temporary or permanent breakdown, malfunction or damage of or to any premises, plant, equipment (including computer systems) or materials; (iii) any breach of contract, default or insolvency by or of any Independent Third Party, other than an Affiliate of the Party affected by the force majeure, or an employee or officer of that Party or Affiliate; (iv) any action taken by a governmental or public authority imposing an embargo, export or import restriction, rationing, quota or other restriction or prohibition; (v) any civil commotion or disorder, riot, invasion, war, threat of or preparation for war; or (vi) any accident, fire, or explosion, (other than in each case, one caused by a breach of contract by or assistance of the Party concerned) storm, flood, earthquake, subsidence, epidemic or other natural physical disaster. Notwithstanding the foregoing, lack of funds, manpower or equipment, interruption or failure of utility service and the fault or misconduct by any personnel engaged by a Party shall not be an event of Force Majeure.

20.9 Relationship of the parties

- (A) Nothing in this Agreement shall constitute, or be deemed to constitute, a partnership between the Parties nor, except as expressly provided, shall it constitute, or be deemed to constitute, any Party the agent of any other Party for any purpose.
- (B) Subject to any express provisions to the contrary in this Agreement, neither Party shall have any right or authority to and shall not do any act, enter into any contract, make any representation, give any warranty, incur any liability, assume any obligation, whether express or implied, of any kind on behalf of the other Party or bind the other Party in any way.
- (C) Nothing in this Agreement shall oblige either Party to (i) infringe any intellectual property rights or other rights of any person who is not a Party to this Agreement or (ii) do or omit to do anything other than in accordance with all applicable laws.

20.10 Counterparts

This Agreement may be executed in any number of counterparts, which shall together constitute one Agreement. Any Party may enter into this Agreement by signing any such counterpart.

20.11 Third Party Rights

Except for Affiliates of the Parties under Clauses 15.1 and 15.2, who may in their own right enforce the provisions of those Clauses, no person who is not a Party to this Agreement shall have any right to enforce any term of this Agreement.

20.12 Governing Law and Jurisdiction

- (A) This Agreement and any non-contractual obligations arising from or connected with it shall be governed by German law and this Agreement shall be construed in accordance with German law.
- (B) Subject to Clauses (C) and (D), any dispute arising out of or in connection with this Agreement, including any question regarding the existence, scope, validity, or termination of this Agreement or this Clause, the legal relationships established by this Agreement or the consequences of its nullity (and including any tortious or statutory claims), shall be referred to and finally resolved by arbitration under the rules of the International Court of Arbitration of the International Chamber of Commerce ("Rules"), and the Rules are deemed to be incorporated by reference into Clause 20.12(B), save, that notwithstanding anything in the Rules, the Parties preserve their right to appeal or refer to the German Courts on questions of law. The number of arbitrators shall be three (3), one (1) to be nominated by each Party and the third (the chairman) to be appointed by the International Court of Arbitration. The Parties shall provide their nominations for arbitrators within thirty (30) days following service of the request for arbitration under the Rules. The place of the arbitration shall be Frankfurt, Germany. The arbitration proceedings shall be conducted in the English language and any award shall be in English.

- (C) Each of the Parties agrees that if certain material obligations under this Agreement are not performed in accordance with their specific terms or are otherwise breached, (i) severe and irreparable damage would occur, and (ii) no adequate remedy at law would exist, and (iii) damages would be difficult to determine. Each of the Parties agrees that, in such case, the injured Party shall be entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, as well as any other relief permitted by applicable law.
- (D) In respect of any dispute relating to the determination of scope, validity or enforceability of any intellectual property rights, the Parties consent to the exclusive jurisdiction of the courts of the country the laws of which cause that intellectual property right to come into being and where such courts have jurisdiction the dispute shall be determined according to the laws of that country.

Signature page follows

AS WITNESS the Parties hereof have executed this Agreement the day and year first before written.

Ascendis Pharma A/S

Signed by: /s/ Jan Møller Mikkelsen
Jan Møller Mikkelsen
President and CEO

Sanofi-Aventis Deutschland GmbH

Signed by: /s/ Dr. Martin Siewert
Dr. Martin Siewert
Chief Executive Officer

Signed by: /s/ Michael Wolff Jensen
Michael Wolff Jensen
Chairman of the Board of Directors

Signed by: /s/ Dr. Klaus Menken
Dr. Klaus Menken (CFO Germany)
Chief Financial Officer

SCHEDULE 1: PATENTS

Part I: Product Patents

Part I: Product Patent Applications/Patents

[***]

Part II: Technology Platform Patent Applications/Patents

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE 2: SHORT FORM PATENT LICENCE

THIS AGREEMENT is made the [] day of []

BETWEEN:

- (1) **ASCENDIS PHARMA A/S**, ("Ascendis"), a company registered in Denmark with its registered office at Tuborg, Boulevard 12, DK-2900 Hellerup, Denmark; and
- (2) **SANOFI AVENTIS DEUTSCHLAND GmbH**, ("Sanofi"), a company registered in Germany with its registered office at Industriepark Hoechst 65926 Frankfurt, Germany.

Ascendis hereby grants to Sanofi an exclusive licence for exploitation, [for all diseases] [in the field of diabetes], of the patent(s) set out in the Schedule below within [insert relevant country] subject to and terminable in accordance with the terms and conditions of an agreement between the Parties hereto dated [].

Appendix

[insert details of relevant patents/patent applications]

AS WITNESS the Parties have executed this Agreement the day and year first above written.

Signed by)
For and on behalf of)
Ascendis Pharma A/S)

Signed by)
For and on behalf of)
Sanofi-Aventis Deutschland GmbH)

SCHEDULE 3: TECHNICAL INFORMATION

Ascendis Pharma's TransCon technology encompasses the combination of linkers [***]. The linker families are a diverse group of structures with inherent chemical self-cleaving properties. Ascendis Pharma's transient conjugation allows for a drug compound to be released in the body in a precise, time-controlled fashion, creating a long-acting effect for the original unmodified drug. Ascendis Pharma's TransCon Hydrogel carrier is [***].

The documents in the following list describe the Technical Information that Ascendis will provide to Sanofi pursuant to Clauses 3.1 and 4.5:

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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SCHEDULE 5: LICENCES GRANTED TO ASCENDIS

None as of the Effective Date.

Part I: Business Team

[***]

Part II: Individuals subject to non-compete undertakings

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE 7: LIST OF FILING COUNTRIES

***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

WARRANT CERTIFICATE
(non-negotiable instrument)

Ascendis Pharma A/S, Hellerup Boulevard 12, DK-2900 Hellerup (hereinafter referred to as Ascendis Pharma), cvr.nr. 29 91 87 91, has on [date of grant] issued this Warrant Certificate to

[adresse]

(hereinafter referred to as the "Warrantholder")

whereby the Warrantholder without payment has received and accepted allocation of [number] warrants, which confer the right to subscribe [number] A-shares in Ascendis Pharma at a subscription price of DKK [price] per share with a nominal value of DKK 1. The other terms applying to the warrants have been set forth in Ascendis Pharma's articles of association clause 4b with appendix [1][2], which is attached to this Warrant Certificate.

Shareholder's Agreement

A shareholders' agreement between Ascendis Pharma's shareholders and the warrantholders, which shall apply to the extent that the shares are subscribed through exercise of warrants, has been attached. The issuance of warrants according to this Warrant Certificate is conditional upon the Warrantholder accepting said shareholders' agreement.

This Warrant Certificate is issued in two original copies with one original copy Ascendis Pharma and one original for the Warrantholder. By signing this certificate, the Warrantholder accepts to have received the issued warrants on the above terms.

Place: _____, [date]

Hellerup, [date]

[Name]

Michael Wolff Jensen, Chairman

Ascendis Pharma A/S

Subsidiaries of the Registrant

Name

Ascendis Pharma GmbH
Ascendis Pharma, Inc.
Ascendis Pharma, Growth Disorders Division A/S
Ascendis Pharma, Ophthalmology Division A/S
Ascendis Pharma, Osteoarthritis Division A/S
Ascendis Pharma, Circulatory Diseases Division A/S

Jurisdiction of Incorporation

Germany
Delaware, USA
Denmark
Denmark
Denmark
Denmark