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

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended December 31, 2025

OR

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

For the transition period from _____ to

OR

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

Date of event requiring this shell company report

Commission file number: 001-36815

Ascendis Pharma A/S

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

The Kingdom of Denmark
(Jurisdiction of incorporation or organization)

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

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

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

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

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

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

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

61,977,408 ordinary shares (including 597,096 ordinary shares represented by ADSs held by the registrant and its consolidated subsidiaries)
(as of December 31, 2025)

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

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

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

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

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

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

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

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

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

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

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

Auditor Firm ID:	**Auditor Name:**	**Auditor Location:**
1294	**Deloitte Statsautoriseret Revisionspartnerselskab**	**Copenhagen, Denmark**

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General

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

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

Special Note Regarding Forward-Looking Statements

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

- the timing or likelihood of regulatory filings and approvals for our products and product candidates;
- our expectations regarding the commercial availability of our approved products;
- the commercialization of our products and product candidates, if approved for commercial use;
- our commercialization, marketing, and manufacturing capabilities of our products and product candidates and associated devices;
- the scope, timing, progress, results and costs of developing our product candidates or any other future product candidates, and the timing, conduct, and results of preclinical studies and clinical trials;
- our pursuit of oncology as an independent therapeutic area of focus and our development of product candidates related to oncology;
- Eyconis's ability to develop, manufacture, and commercialize TransCon ophthalmology assets globally;
- our expectations regarding the potential market opportunities and patient populations for our products and product candidates, if approved for commercial use;
- our expectations regarding the potential advantages of our products and product candidates over existing therapies;
- our existing collaborations and license agreements and our ability to enter into new collaborations and license agreements;
- the potential benefits of using our products and product candidates in combination with each other and other therapies;
- our expectations with regard to the ability to develop additional product candidates using our TransCon technologies and submit Investigational New Drug Applications ("INDs") or similar for such product candidates;
- our ability to benefit from established data of clinically validated parent drugs or pathways to which we apply our TransCon technologies;

- our expectations with regard to our current and future collaboration partners to pursue the development of our product candidates and submit INDs or similar for such product candidates;
- our development plans with respect to our products and product candidates;
- our pursuit of additional indications for our products;
- the implementation of our business model and strategic plans for our business, our products and product candidates and technologies, including global commercialization strategies;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products and product candidates;
- our expectations regarding our ability to apply our technology platform and algorithm for product innovation to develop highly differentiated product candidates to address unmet medical needs;
- our ability to apply our TransCon technology platform to develop new therapies that demonstrate best-in-class potential to address unmet medical needs;
- our application of TransCon technology platform to make a meaningful difference for patients;
- our goals for Vision 2030;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our financial performance;
- our ability to attract and hire qualified personnel;
- developments and projections relating to our market conditions, competitors and industry;
- our expectations with respect to ongoing and potential litigation; and
- the impact on our business of international economic, political, legal, compliance, social and business factors, including inflation, tariffs, geopolitical conflicts and energy shortages.

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

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

Additionally, certain information included herein or elsewhere (such as our website) is informed by various stakeholder expectations or third-party frameworks, and therefore should not necessarily be interpreted as rising to the level of materiality as defined under U.S. federal securities laws and regulations, even if we use the language "material" or "materiality." Particularly in the ESG context, materiality is subject to varying definitions that are often different (and more expansive) than the concept for U.S. federal securities laws purposes.

Summary of Material Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties, including those described in "Item 3.D - Key Information - Risk Factors" in this annual report. You should carefully consider these risks and uncertainties when investing in our ADSs. The principal risks and uncertainties affecting our business include the following:

- We may incur significant losses in the future, which makes it difficult to assess our future viability.
- We may seek additional financing to achieve our goals, and a failure to obtain this capital if needed on acceptable terms, or at all, could force us to delay, limit, scale back or cease our commercialization activities, product development or any other or all operations.
- We are substantially dependent on the success of our products and product candidates, which may not be successful in nonclinical studies or clinical trials, receive regulatory approval or be successfully commercialized.
- Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may encounter substantial delays in our clinical studies. Furthermore, results of earlier studies and trials may not be predictive of results of future trials.
- Our sales and marketing efforts may not be effective and we may not be successful in our commercial efforts.
- Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Competition in the biotechnology and pharmaceutical industries is intense and our competitors may discover, develop or commercialize products faster or more successfully than us. If we are unable to compete effectively, our business, results of operations and prospects will suffer.
- We rely on third-parties to manufacture preclinical, clinical and commercial supplies of our products, product candidates and their device components.
- Our operating results may vary significantly from period to period and these variations may be difficult to predict.
- The parent drug, drug product and other components of our products and product candidates are currently acquired from certain single-source suppliers. The loss of these suppliers, or their failure to supply could materially and adversely affect our business.
- Our business has been, and may continue to be, adversely affected by health epidemics, pandemics and other outbreaks of infectious disease.
- Unfavorable global and regional economic, political, health, climate and other conditions and events could adversely affect our business, financial condition or results of operations.
- The regulatory approval processes of the European Medicines Agency ("EMA"), the U.S. Food and Drug Administration ("FDA"), the European Commission ("EC"), the UK Medicines and Healthcare products Regulatory Agency ("MHRA") 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.
- 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.
- If we are sued for allegedly infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in such litigation could harm our business.

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

PART I

Item 1 Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2 Offer Statistics and Expected Timetable

Not applicable.

Item 3 Key Information

A. Reserved

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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

Risks Related to Our Operations, Financial Condition and Capital Requirements

We may incur significant losses in the future, which makes it difficult to assess our future viability.

We are applying our innovative TransCon technology platform to build a leading, fully integrated biopharma company focused on making a meaningful difference in patients' lives. Guided by our core values of patients, science, and passion, we use our TransCon technologies to create new and potentially best-in-class therapies. We currently have a pipeline of multiple independent endocrinology rare disease, and oncology candidates in development. We are also working to apply our TransCon technology platform in additional therapeutic areas to address unmet medical needs. On August 25, 2021, the FDA approved TransCon hGH, known by its brand name SKYTROFA and its international nonproprietary name lonapegsomatropin-tcgd in the U.S. for the treatment of pediatric patients one year and older who weigh at least 11.5 kg (25.4 lb) and have growth failure due to inadequate secretion of endogenous growth hormone, and on July 25, 2025, the FDA approved SKYTROFA for the replacement of endogenous growth hormone in adults with growth hormone deficiency ("GHD"). On August 9, 2024, the FDA approved TransCon PTH, known by its brand name YORVIPATH, for the treatment of hypoparathyroidism in adults. SKYTROFA (lonapegsomatropin) was granted marketing authorization by the EC as a once-weekly subcutaneous injection for the treatment of children and adolescents ages 3 to 18 years with growth failure due to insufficient secretion of endogenous growth hormone on January 11, 2022. In addition, in November 2023, the EC granted marketing authorization to YORVIPATH (palopegteriparatide), as a replacement therapy indicated for the treatment of adults with chronic hypoparathyroidism.

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 relating to our products, YORVIPATH and SKYTROFA, our product candidate TransCon CNP, our product candidates in oncology and our proprietary TransCon technologies, as well as on the commercialization of YORVIPATH and SKYTROFA in the United States. We have a limited commercial operating history upon which our shareholders and ADS holders can evaluate our business and prospects. Going forward, we may incur significant losses from our operations. We had a net loss of €228 million for the year ended December 31, 2025, and a net loss of €378.1 million for the year ended December 31, 2024. Our total equity presented a deficit of €162.8 million as of December 31, 2025, compared to a deficit of €105.7 million as of December 31, 2024. The net loss we have experienced in 2025 is not necessarily indicative of our future results.

Apart from the FDA's, the EC's and MHRA's respective approval of YORVIPATH and SKYTROFA, none of our other product candidates have been approved for commercial sale by the FDA, the EC or similar non-U.S. regulatory authorities. Our annual operating expenses may increase over the next several years as we incur additional commercialization expenses and continue our research and development expenses. Although we receive revenue from commercial product sales, we may incur substantial operating losses for the foreseeable future as we execute our operating plan.

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

We rely significantly on our TransCon technologies and TransCon products and product candidates.

Our ability to generate revenue will continue to depend significantly on our ability to successfully commercialize YORVIPATH and SKYTROFA (and any other approved products) in the U.S. and the EU, complete the research and development of our other product candidates and obtain the regulatory and marketing approvals necessary to commercialize such product candidates. Our ability to generate additional revenue from commercial product sales from SKYTROFA, YORVIPATH or other product candidates or approved products, or pursuant to milestone payments or royalties from collaboration partners depends heavily on many factors, including but not limited to:

- completing research and development of our product candidates;
- obtaining additional regulatory approvals and pricing and reimbursement approvals for our products and product candidates on our own, or together with our strategic collaboration partners;
- negotiating favorable terms of and entering into collaboration, licensing or other arrangements;
- our ability to commercialize or co-promote, and/or the ability of our collaboration partners to successfully commercialize, our products and product candidates;
- developing and sustaining a scalable manufacturing process for our products and product candidates, if approved;
- the market opportunities and patient populations for our products and product candidates, if approved;
- obtaining market acceptance of our products and 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;
- our ability to prevent, avoid, and possibly recover from severe cyber attack(s) with impact on our intellectual property, e.g., data breach and ransomware attacks;

- our ability to prevent, avoid, and possibly recover from severe geopolitical events with impact on our clinical development, manufacturing, and commercial activities; and
- attracting, hiring, and retaining qualified personnel.

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

In addition, our revenue includes provision for a variety of sales deductions such as prompt pay discounts, shelf stock adjustments and applicable sales deductions attributable to various commercial arrangements, managed healthcare organizations, government programs, and co-pay arrangement. Provisions for sales deductions attributed to commercial arrangements are recognized when the related sales take place and measured using the expected value method. Provisions for unsettled sales deductions and product returns are estimated on the basis of a percentage of sales as defined by individual agreements and contracts, and for government rebates by individual state- and plan agreements. Further inputs to the calculations are based on payer channel mix, current contract prices under eligible programs and current inventory levels in the distribution channels. Inputs to the calculations are subject to estimation and assumptions and are based on historical experience and other factors that are relevant, and which are available at the reporting date. These estimates and assumptions are subject to material uncertainties and could result in outcomes that require a material adjustment in future periods.

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

Since our inception, most of our resources have been dedicated to our research and development and commercialization activities. We have funded our operations primarily through issuance of shares and convertible debt securities, royalty arrangements with third parties, and payments to us under collaboration agreements. As of December 31, 2025, we had cash and cash equivalents totaling €616 million. We believe that we will continue to expend substantial resources for the foreseeable future, including costs associated with research and development and commercialization activities. We maintain the majority of our cash and cash equivalents in accounts with major financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

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

- the manufacturing, selling and marketing costs associated with our products and product candidates, if approved, including the cost and timing of building our sales and marketing capabilities;
- the timing, receipt, and amount of sales of, or royalties on, our products and any future products;

- the sales price and the availability of adequate third-party coverage and reimbursement for our products and product candidates, if approved;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to collect payments which are due to us from customers and collaboration partners (if any), which in turn is impacted by the financial standing of any such customers and collaboration partners;
- the progress, timing, scope, results and costs of our preclinical studies and clinical trials and manufacturing activities for our products and product candidates, including the ability to enroll patients in a timely manner for clinical trials;
- the time and cost necessary to obtain regulatory approvals for our products and product candidates and the costs of post-marketing studies that could be required by regulatory authorities;
- the cash requirements of any future acquisitions or discovery of products or 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 platform;
- the achievement of development, regulatory and commercial milestones resulting in the payment to us from collaboration partners of contractual milestone payments and the timing of receipt of such payments, if any;
- our progress in the successful commercialization and co-promotion of our products and product candidates, if approved, and our efforts to develop and commercialize our other existing product candidates;
- the market opportunities and patient populations for our products and product candidates, if approved, and our ability to obtain market acceptance of our products and product candidates, if approved;
- 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; and
- the extent to which we purchase ADSs prior to granting rights or awards for such shares under our equity incentive plans.

Additional funds may not be available if we need them or 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 and commercialization activities.

Raising additional capital may cause dilution to our holders of shares or ADSs, restrict our operations or require us to relinquish rights to our products or 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 or royalty arrangements with third parties. To the extent that we raise additional capital through the issuance of convertible debt or equity securities, the ownership interest of our shareholders and ADS holders may be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our shareholders and ADS holders. Such financing may result in dilution to holders of shares or ADSs, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic partnerships with third-parties, we may have to relinquish valuable rights to our products or 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.

For example, in September 2023, we entered into a $150.0 million capped synthetic royalty funding agreement (the "SKYTROFA Agreement"), with Royalty Pharma. Under the terms of the SKYTROFA Agreement, we received an upfront payment of $150.0 million in exchange for a 9.15% royalty on net U.S. SKYTROFA revenue. In September 2024, we entered into a $150.0 million capped synthetic royalty funding agreement with Royalty Pharma (the "YORVIPATH Agreement", and together with the SKYTROFA Agreement, the "Royalty Pharma Agreements"). Under the terms of the YORVIPATH Agreement, we received an upfront payment of $150.0 million in exchange for a 3.0% royalty on net U.S. YORVIPATH revenue.

Risks Related to Our Business

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

To date, we have invested a significant amount of our efforts and financial resources in research and development, including with respect to our proprietary TransCon technologies, and in commercialization activities. Our near-term prospects, including the extent of revenue from commercial product sales, will depend heavily on our successful development and commercialization of our products and product candidates, if approved. The clinical and commercial success of our products and product candidates and our TransCon technologies will depend on a number of factors, including the following:

- the outcome and successful execution of our ongoing and planned clinical trials of our products and product candidates;
- our ability and that of any collaboration partners to establish and maintain commercial-scale manufacturing processes for our products, product candidates and device components;
- whether our product candidates' safety, purity, potency, tolerability and/or efficacy profiles will be satisfactory to the EMA/EC, the FDA and similar regulatory authorities to warrant marketing approval;
- whether the EMA/EC, the FDA or similar regulatory authorities will require additional clinical trials prior to approving or issuing a positive opinion in order for our product candidates to be authorized, if ever;
- the prevalence and severity of adverse side effects of our products and product candidates;
- the occurrence of adverse events that implicate the TransCon technologies, including among any out-licensed product candidates;
- the timely receipt of necessary marketing authorizations or certifications for our product candidates and associated device components from the FDA, similar regulatory authorities and notified bodies;
- our ability and that of any collaboration partners to successfully commercialize our products or product candidates, if approved for marketing and sale by the FDA, the EC 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;
- our expectations regarding the potential market opportunities and patient populations for our products and product candidates;
- our progress in the successful commercialization and co-promotion of our products and product candidates, if approved, and our efforts to develop and commercialize our other existing product candidates;
- our ability to obtain market acceptance of our products or product candidates, if approved, including by patients and the medical community;
- our ability to obtain market acceptance of the device components of our combination products, and of our combination product candidates, if approved, including 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 products and product candidates by third-party payors;
- the effectiveness of our and any collaboration partners' marketing, sales and distribution strategies and operations;
- our ability and that of any collaboration partners, or any third-party manufacturer we contract with, to manufacture supplies of our products and product candidates and to develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practice ("cGMP"), or similar requirements;
- enforcing intellectual property rights in and to our products and 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 products and product candidates following any potential approval.

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

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

Our sales and marketing efforts may not be effective and we may not be successful in our commercial efforts.

While we launched SKYTROFA in 2021 and YORVIPATH in late 2024, we have limited experience successfully scaling commercial operations for multiple products simultaneously. The success of our commercialization efforts is difficult to predict and subject to the effective execution of our business plan, including, among others, the continued development of our internal sales, marketing, and distribution capabilities and our ability to navigate the significant expenses and risks involved with the development and management of such capabilities. For example, our commercial launch of YORVIPATH in the United States may not develop as planned or anticipated, which may require us to, among others, adjust or amend our business plan and incur significant expenses. Further, given our limited experience commercializing products, we do not have a long track record of successfully executing commercial launches. If we are unsuccessful in accomplishing our objectives and executing on our business plan, or if our commercialization efforts do not develop as planned, we may not be able to successfully commercialize our approved products and any future approved products, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry.

Factors which may affect the success of our commercialization efforts include, but are not limited to:

- our ability to hire and retain required and qualified sales and marketing personnel, including in connection with any specialty sales organization for specific products or product candidates, if approved;
- our ability to provide sufficient training to develop and strengthen the technical expertise of our sales and marketing personnel;
- our ability to provide required support materials and resources to our sales personnel to help them educate physicians and healthcare providers regarding our products, including the proper administration of our products; and
- our resources to meet and timely fulfill supply obligations to our customers.

Additionally, we or any collaboration partners may be required to build and/or maintain marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third-parties to perform these services, and we or any collaboration partners may not be successful in doing so. In addition, arrangements we enter into with third-parties to market and sell our products and product candidates, if approved, in one or multiple geographies might not be successful, and we may not be able to enter into such arrangements with others on acceptable terms, or at all. To the extent that we enter into such 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.

The acceptance and commercial success of our products and product candidates, if approved, will depend, in part, upon the degree of acceptance among physicians, patients, patient advocacy groups, third-party payors and the medical community.

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

- the safety, purity, potency and/or efficacy of the products as demonstrated in clinical trials;
- the prevalence and severity of any side effects and overall safety profile of the product;
- the perceived safety of the TransCon technologies;
- the convenience and features of the auto-injector or drug delivery device used to administer the drug;
- the clinical indications for which the product is approved;

- education of, and 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 products 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 products;
- the quality of our relationships with patient advocacy groups; and
- coverage and reimbursement policies of government and other commercial and third-party payors.

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

Our estimated market opportunities for our products and product candidates, if approved, are subject to numerous uncertainties and may prove to be inaccurate. If we have overestimated the size of our market opportunities, our future growth may be limited.

Our business plan is based in part on our estimated addressable markets and market opportunities for our products and product candidates, if approved, which are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and there can be no assurance as to its accuracy or completeness. Such estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. While we believe the market opportunity estimates underlying our business plan are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this annual report. If this third-party or internally generated data prove to be inaccurate or we make errors in our assumptions based on that data, our actual market may be more limited than our estimates. In addition, these inaccuracies or errors may cause us to misallocate capital and other critical business resources, which could harm our business.

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

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

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

- generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- reach consensus with regulatory authorities on study design or implementation of the clinical trials and/or obtain regulatory authorization to commence a trial;
- reach agreement on acceptable terms with prospective contract research organizations, 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;
- identify, recruit and train suitable clinical investigators;
- obtain institutional review board ("IRB"), or ethics committee approval at each site;
- manufacture, test, release, validate or import sufficient quantities of drug product for use in a trial;
- recruit, screen and enroll suitable patients to participate in a trial;
- have patients complete a trial or return for post-treatment follow-up;
- ensure that clinical sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations; or
- initiate or add a sufficient number of clinical trial sites.

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

We could also encounter delays if a clinical trial is suspended or terminated by us for a product candidate, by the IRBs of the institutions in which such trials are being conducted, by an independent data safety monitoring board, for such trial or by 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 the FDA or similar regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, we are conducting, and plan to conduct, clinical trials in sites outside of the United States and the EU. 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/EC or the FDA may determine that the clinical trial results obtained in foreign subjects do not establish the safety, purity, potency and/or efficacy of a product candidate when administered in EU or U.S. patients, and are thus not supportive of granting of a marketing authorization application ("MAA"), in the EU or of a New Drug Application ("NDA"), or Biologics License Application ("BLA"), in the United States. As a result, the EMA or the FDA may not accept data from clinical trials conducted outside the EU or the United States, respectively, and may require that we conduct additional clinical trials or obtain additional data before we can submit an NDA or BLA in the United States or a MAA in the EU. The EMA or the FDA may even require us to conduct additional clinical trials in the EU or the United States, respectively, before we are able to submit an NDA, BLA, MAA or other marketing application for any of our product candidates.

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

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation ("EU CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application ("CTA"), to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the EU CTR introduced a centralized process and only requires the submission of a single application for multi-center trials. The EU CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU IT portal. Once the CTA is approved, clinical study development may proceed. One of the main aims of EU CTR is to increase transparency about clinical trials, which is done by making documents and data from the CTA publicly available through the Clinical Trials Information System at the time of decision about the clinical trial. There are few exceptions to this, and release of personal data and company confidential information may be controlled through redaction. The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR. Compliance with the EU CTR requirements by us and our third-party service providers, such as CROs, may impact our development plans.

Furthermore, on April 28, 2025, the UK adopted an amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 intended to support a more streamlined and flexible regulation of clinical trials, removing unnecessary administrative burdens on trial sponsors, while protecting the interests of trial participants. It also intends to bring the UK regulatory framework for clinical trials, which is still based on the EU Clinical Trials Directive, into closer alignment with the EU CTR. The amendment will become applicable on April 28, 2026 following a one-year transition period.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be adversely impacted.

Certain of our product candidates are in various stages of preclinical development and we may not be successful in our efforts to successfully develop these products or expand our pipeline of product candidates.

A key element of our strategy is to expand our pipeline of product candidates utilizing our proprietary TransCon technologies, and to advance such product candidates through clinical development. Certain of our product candidates are in preclinical development and may require significant time and additional research and development before we can submit Investigational NDAs, CTAs or other equivalent foreign regulatory applications to regulatory authorities to begin clinical studies. Of the large number of drugs and biologics in development, only a small percentage of such drugs successfully complete the EMA/EC or FDA regulatory approval process and are commercialized. Accordingly, even if we are able to continue to fund such development programs, our product candidates may not be advanced to clinical studies or be successfully developed or commercialized. In addition, our preclinical product candidates may not demonstrate the advantages we expect from application of our TransCon technologies in preclinical studies. In such event, we may decide not to progress any such product candidates into clinical trials.

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

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

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

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

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

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

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

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

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

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

We do not currently have the ability to independently conduct clinical trials or IND-enabling 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 products and product candidates. The third-parties with whom we contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third-parties are not our employees, and except for contractual duties and obligations, we control only certain aspects of their activities and have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third-parties to conduct our nonclinical studies and our clinical trials, we remain responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with the applicable protocol, scientific standards and legal and regulatory requirements, 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 ("GLPs"), for certain nonclinical studies, and good clinical practices ("GCPs"), for clinical studies. GLPs and GCPs are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products in nonclinical and clinical development, respectively. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third-party contractors fail to comply with applicable regulatory requirements, including GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the EMA, the FDA, or similar regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be certain that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP or similar foreign regulations outside the United States. 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.

Our products and 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 any of our approved products or 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 FDA or similar authorities. In the event that trials conducted by us or any collaboration partners, or trials we conduct with our product candidates, reveal a high and unacceptable severity and prevalence of side effects, such trials could be suspended or terminated and the FDA or similar regulatory authorities could order any collaboration partners or us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

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

- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or any collaboration partners, may be required to recall the product;

- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof, including the imposition of a REMS or requirements for similar actions, such as patient education, certification of health care professionals or specific monitoring;
- we, or any collaboration partners, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us, or any collaboration partners, from achieving or maintaining market acceptance of our products or product candidates, 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 products and 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 products and 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 our products and 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. A permanently PEGylated long-acting growth hormone (brand name Jintrolong®) developed by GeneScience Pharmaceuticals Co., Ltd. is available in China and the Somatropin Biopartners product (LB03002), is available in Korea. Novo Nordisk has received regulatory approval of once-weekly somapacitan (brand name SOGROYA®) for replacement of endogenous growth hormone in adult patients with GHD in the United States, Japan, Europe, Australia and Saudi Arabia and in pediatric patients with GHD in the United States, Japan, Europe, Canada, Brazil and Saudi Arabia. Pfizer (in collaboration with OPKO Health Inc.) has received regulatory approval of once-weekly somatrogon (brand name NGENLA) in more than 40 countries for pediatric GHD. Other experimental growth hormone therapies are in different stages of clinical development by various companies, including Genexine Inc., I-MAB, and JCR Pharmaceuticals Co., Ltd. In addition, we are aware of several academic groups and companies working on making longer-acting agonists of the PTH receptor ("PTH1R"). Other companies and groups are developing or commercializing therapies for hypoparathyroidism, including Calcilytix (a BridgeBio company), Entera Bio, Extend Biosciences, Massachusetts General Hospital, Amolyt Pharma, and MBX Biosciences. Other companies are developing therapies for achondroplasia, including BioMarin Pharmaceutical, Inc. ("BioMarin"), and QED Therapeutics (a BridgeBio company). BioMarin has received regulatory approval for vosoritide (brand name VOXZOGO®) in more than 40 active markets for the treatment of achondroplasia and is developing BMN 333, a long-acting C-type natriuretic peptide ("CNP") for multiple growth disorders. Tyra Biosciences, Sanofi, ProLynx Inc. and Ribomic, Inc., have achondroplasia programs in various clinical stages.

Other companies have Interleukin 2 program under development for cancer immunotherapy including: Mural Oncology plc, Medicenna Therapeutics Corp., Anaveon AG, Xilio Therapeutics Inc, Werewolf Therapeutics Inc., Sutro Biopharma Inc. and Philogen SpA.

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

It is also possible that our competitors will commercialize competing drugs or treatments before we can launch any other product candidates that are ultimately approved by regulatory authorities. We also anticipate that we will face increased competition in the future as new companies enter into our current and target markets.

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

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

Any one of these strategies may increase the costs and risks associated with our efforts to develop and commercialize our products and product candidates and may delay or altogether prevent such development or commercialization.

Many of our competitors have:

- significantly greater name recognition, financial, marketing, research, drug portfolios, 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.

With respect to our products and product candidates that we successfully develop, we will face competition based on many different factors, including:

- the safety and effectiveness of such 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;
- the product's convenience and ease of administration compared to alternative treatments; and
- the strength of our patent position.

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

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

Our proprietary TransCon technology platform includes a novel approach to extending the residence time and duration of action of a variety of drug products.

Our TransCon technology platform has been developed to improve the delivery of a variety of drug products. However, we cannot be certain that any of our other products or product candidates using our TransCon technologies will be deemed safe, pure, potent or efficacious (or that any of our products will be deemed safe, pure, potent or effective for other indications), nor that any aspects of our TransCon technologies will yield additional product candidates that could be commercially valuable. Further, our TransCon hydrogel carrier system has limited experience in humans and our drug molecules based on albumin avidity has no experience in humans. As a result, our TransCon hydrogel carriers and our albumin avidity based drug molecules, when dosed extensively in humans, may fail to perform as we expect. Failure of any of our product candidates to be successfully developed, approved and commercialized may result in our TransCon technologies being viewed as an ineffective approach to developing drug products which would harm our business and prospects.

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

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

Our products and product candidates are designed to 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 regarding utilizing the systemic TransCon technologies to indicate whether they are safe, pure, potent and/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. If treatment with any of our product candidates in our clinical trials results in concerns about their safety or efficacy, we and any collaboration partners may be unable to successfully develop or commercialize any or all of our TransCon technologies based on such product candidates or enter into collaborations with respect to our product candidates.

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

We rely on our collaboration partners to conduct certain clinical studies. For example, in November 2018, we announced the formation of VISEN Pharmaceuticals ("VISEN"), a company established to develop, manufacture, and commercialize our endocrinology rare disease therapy candidates in Greater China, which completed a Hong Kong Stock Exchange listing in 2025. In connection with the formation of VISEN, we granted VISEN exclusive rights to develop and commercialize our rare disease endocrinology products based on our proprietary TransCon technologies, including TransCon hGH, TransCon PTH and TransCon CNP, in Greater China for use in all human indications, subject to certain exceptions. As another example, in November 2023, we announced that we entered into an exclusive license agreement with Teijin Limited, ("Teijin"), to develop and commercialize TransCon hGH, TransCon PTH and TransCon CNP for certain endocrinology rare diseases in Japan. As a further example, in January 2024, we announced the formation of Eyconis, Inc. ("Eyconis"), a separate company created to develop, manufacture, and commercialize TransCon ophthalmology assets globally, together with an investor syndicate. In connection with the formation of Eyconis, we granted Eyconis exclusive rights to develop and commercialize TransCon ophthalmology products globally and received an equity position in the newly formed company. We may also enter into collaboration agreements with other parties relating to our other product candidates and technology platform. For example, in November 2024, we entered into a research and development collaboration and license agreement with Novo Nordisk A/S ("Novo Nordisk"), pursuant to which we granted Novo Nordisk an exclusive worldwide license to our TransCon technology platform to develop, manufacture and commercialize Novo Nordisk proprietary products in metabolic diseases and a product-by-product exclusive license in cardiovascular diseases.

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

- our collaboration partners may have the unilateral ability to choose not to develop a collaboration product or product candidate for one or more indications for which such product or product candidate 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 or commercialize our collaboration product or product candidate in certain relevant markets;
- our collaboration partners may take considerably more time in advancing our product or product candidate 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 or royalties from our collaboration partners;
- our collaboration partners may have substantial discretion under their respective agreements regarding how they structure their efforts and allocate resources to fulfill their obligations to diligently develop, obtain regulatory approval for and commercialize our collaboration products and product candidates;

- our collaboration partners may control all or substantially all of the aspects of development and/or commercialization efforts under their respective license agreements and may change the focus of their development and/or commercialization efforts or pursue other higher-priority programs and, accordingly, reduce the efforts and resources allocated to their collaborations with us;
- our collaboration partners may solely be responsible for or have substantially all of the responsibility related to obtaining and maintaining all regulatory approvals of our products or product candidates, and we or our collaboration partners may fail to develop a commercially viable formulation or manufacturing process for our products or product candidates, and we or our collaboration partners may fail to manufacture or supply sufficient drug substance for commercial use, if approved, which could result in lost revenue under such collaborations;
- our collaboration partners may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- if any of our agreements with our collaboration partners terminate, we would need to identify alternative means to continue the development, manufacture and commercialization of the affected products or product candidates, alone or with others;
- our collaboration partners may have the discretion to sublicense their rights with respect to our collaboration technology in connection with collaboration products and product candidates to one or more third-parties without our consent;
- our collaboration partners may be pursuing alternative technologies or developing alternative products or product candidates, either on their own or in collaboration with others, that may be competitive with our technology, products or product candidates on which they are collaborating with us or which could affect our collaboration partners' commitment to the collaboration; and
- our collaboration partners may experience financial difficulties.

The timing and amount of any milestone and royalty payments we may receive under agreements with collaboration partners and the value of any equity we own in our collaboration partners (such as the equity we own in VISEN and Eyconis) will depend on, among other things, the efforts, allocation of resources, and successful development and commercialization of our products or product candidates by our collaboration partners. We cannot be certain that any development and regulatory milestones will be achieved or that we will receive any future milestone payments under agreements we may enter into with collaboration partners. In addition, in certain circumstances we may believe that a particular milestone has been achieved and the applicable collaboration partner may disagree with our belief. In that case, receipt of that milestone payment may be delayed or may never be received, which may require us to adjust our operating plans. We also cannot be certain that any equity we own in our collaboration partners (such as the equity we own in VISEN and Eyconis) will maintain its value or grow in value.

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

We may form strategic collaborations, create joint ventures or similar structures or enter into licensing arrangements with third-parties with respect to our independent programs that we believe will complement or augment our existing business. We have historically engaged, and intend to continue to engage, in partnering discussions with a range of biopharmaceutical companies and could enter into new collaborations at any time. For example, in November 2018, we announced the formation of VISEN, a company established to develop, manufacture, and commercialize our endocrinology rare disease therapies in Greater China. In connection with the formation of VISEN, we granted VISEN exclusive rights to develop and commercialize our rare disease endocrinology products based on our proprietary TransCon technologies, including TransCon hGH, TransCon PTH and TransCon CNP, in Greater China for use in all human indications, subject to certain exceptions. As another example, in November 2023, we announced that we entered into an exclusive license agreement with Teijin to develop and commercialize TransCon hGH, TransCon PTH and TransCon CNP for certain endocrinology rare diseases in Japan. As a further example, in January 2024, we announced the formation of Eyconis, a separate company created to develop, manufacture, and commercialize TransCon ophthalmology assets globally, together with an investor syndicate.

In connection with the formation of Eyconis, we granted Eyconis exclusive rights to develop and commercialize TransCon ophthalmology products globally and received an equity position in the newly formed company. Additionally, in November 2024, we announced that we signed a Exclusive License and Development Agreement with Novo Nordisk A/S for the development and commercialization of TransCon Technology-based products in the fields of metabolic and cardiovascular diseases.

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

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

Regulatory authorities in some jurisdictions, including the United States, may designate drugs or biologics intended to treat relatively small patient populations as orphan drug products. Under the Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, orphan designation is granted by the EC based on a scientific opinion of the EMA's Committee for Orphan Medicinal Products. A medicinal product may be designated as orphan if its sponsor can establish that (i) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than 5 in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the medicinal product will be of significant benefit to those affected by the condition. Orphan designation must be requested before submitting a BLA or NDA in the United States or a MAA in the EU.

If a drug or biologic with an orphan designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug or biologic is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug or biologic for the same approved indication or use within such disease or condition for a seven-year period, except in limited circumstances. If our competitors are able to obtain orphan drug exclusivity prior to us, for products that constitute the "same drug" and are approved for the same indications and uses as we intend to seek for our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time. The applicable period is seven years in the United States. The applicable exclusivity period is ten years in the EU, but such exclusivity period can be reduced to six years if, at the end of the fifth year, a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

As part of our business strategy, we intend to pursue orphan designation for certain of our product candidates. For example, in June 2018, we were granted orphan drug designation by the FDA for TransCon PTH for the treatment of hypoparathyroidism, in February 2019, we were granted orphan drug designation by the FDA for TransCon CNP for the treatment of achondroplasia, and in April 2020, we were granted orphan drug designation by the FDA for TransCon hGH for the treatment of GHD.

Additionally, in October 2019, we were granted orphan designation by the EC for TransCon hGH for GHD, in July 2020, we were granted orphan designation by the EC for TransCon CNP for the treatment of achondroplasia and in October 2020, we were granted orphan designation by the EC for TransCon PTH for treatment of hypoparathyroidism. In July 2021, we were granted orphan drug designation from the Japanese Ministry of Health, Labour and Welfare for TransCon PTH. However, we may be unsuccessful in obtaining additional orphan designations, and may be unable to maintain the benefits associated with orphan designation, such as orphan drug exclusivity.

We have obtained orphan drug exclusivity from the FDA for YORVIPATH for the treatment of hypoparathyroidism in adults, and for SKYTROFA for the treatment of pediatric patients one year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous GH and for the replacement of endogenous growth hormone in adults with GHD. However, even if we obtain orphan drug exclusivity for any of our product candidates, that exclusivity may not effectively protect those product candidates from competition because different drugs can be approved for the same indications and uses within the same rare disease or condition, and orphan drug exclusivity does not prevent the FDA or foreign regulatory authorities from approving the same or a different drug in another indication. Even after an orphan drug is granted orphan exclusivity and approved, the FDA or foreign regulatory authorities can subsequently approve a later application for the same drug for the same condition before the expiration of the exclusivity period if the FDA or foreign regulatory authorities conclude that the later drug is clinically superior in the relevant indication in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan-drug-exclusive marketing rights in the United States and in foreign jurisdictions may be lost if the FDA or foreign regulatory authorities later determine that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs relating to the approved indication or use of patients with the rare disease or condition. Orphan designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Any biological product for which we have obtained approval may face competition sooner than anticipated.

The Affordable Care Act ("ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

Although the majority of our products and product candidates are regulated by the FDA as small-molecule drugs, the FDA regulates TransCon hGH, including the commercial version we market as SKYTROFA, as a biological product, and we may develop future product candidates regulated by the FDA as biologics. We believe that any of our future biological product candidates approved under a BLA should qualify for the twelve-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Jurisdictions in addition to the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the EU has had an established regulatory pathway for biosimilars since 2006. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. For example, in recent years, the FDA has sought to reduce the data required for biosimilar product sponsors to demonstrate biosimilarity to, or interchangeability with, a biologic reference product. In particular, in June 2024, the FDA published updated draft guidance entitled "*Considerations in Demonstrating Interchangeability with a Reference Product*" in which the FDA, among other things, set forth conditions under which interchangeable product sponsors could demonstrate interchangeability without conducting so-called "switching" studies. Similarly, in October 2025, the FDA published a draft guidance entitled "*Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies*" in which the FDA set forth conditions under which biosimilar product sponsors may demonstrate biosimilarity without conducting comparative efficacy studies. Although the FDA has yet to finalize these draft guidance documents, these or similar efforts may increase the risk of competition for our biologic products.

We rely on third-parties to manufacture preclinical, clinical, and commercial supplies of our products, product candidates and their device components.

We do not own facilities for manufacturing our products and product candidates. We depend on third-parties to manufacture and provide analytical services with respect to our products and product candidates and their respective device components.

In addition, to produce the quantities necessary to meet anticipated market demand, we and/or any collaboration partners will need to secure sufficient manufacturing capacity with third-party manufacturers. For YORVIPATH and SKYTROFA, we believe we have secured agreements to provide for sufficient manufacturing capacity with third-party manufacturers; however, our estimates of market demand may be inaccurate and third-party manufacturers may fail to produce sufficient quantities on a timely basis or at all. If we and/or any collaboration partners are unable to produce our products and 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 would be adversely affected. To be successful, our products and product candidates must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. We and/or any collaboration partners will regularly need to maintain access to facilities to manufacture commercial supplies of our products and product candidates, if approved. All of this will require additional funds and successful completion of inspection or audits and approval by the FDA, other regulatory authorities and by notified bodies with respect to the device components. If we and/or any collaboration partners are unable to establish and maintain a manufacturing capacity within our planned time and cost parameters, the development and sales of our products and product candidates as well as our business, results of operations and prospects, and the value of our shares or ADSs could be adversely affected.

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

- production yields;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with FDA and foreign 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 products and 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 products and product candidates can be manufactured under cGMP or similar foreign regulations, a requirement for all pharmaceutical products. We cannot be certain that we will be able to contract with any of these companies on acceptable terms, if at all, all of which could harm our business, results of operations and prospects, and the value of our shares or ADSs.

In addition, we, as well as any third-party manufacturer, will be required to register such manufacturing facilities with the FDA (and have a U.S. agent for the facility, if outside the United States) and other regulatory authorities. The facilities will be subject to inspections confirming compliance with the FDA, and other regulatory authority cGMP or similar foreign requirements. We do not control the manufacturing process of our product candidates, and we are dependent on our contract manufacturing partners for compliance with cGMPs or similar regulations for manufacture of both active drug substances and finished drug products. If we or any third-party manufacturer fails to maintain regulatory compliance, our business, financial condition and results of operations may be harmed, and the FDA 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. Pursuant to our agreements with VISEN, we have provided and may in the future provide, clinical supplies of our product candidates and commercial supplies of our products to VISEN for its use in clinical trials and commercialization. Pursuant to our agreements with Teijin, we may also provide Teijin with clinical supplies of our product candidates and commercial supplies of our products for Teijin's use in future clinical trials and commercialization. In order to fulfill these supplies, we rely on third-party manufacturers over which we have no or very limited control or power.
We may also rely on other foreign contract research organizations ("CROs"), and contract manufacturing organizations ("CMOs"), such as WuXi Biologics. Such foreign CROs and CMOs may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. For example, the U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services from "biotechnology companies of concern" or entering into, extending, or renewing any contracts with entities that use such biotechnology equipment or services from "biotechnology companies of concern." Congress has interpreted a "biotechnology company of concern" as an entity that is under the control of a foreign adversary and that poses a risk to national security based on its research or multiomic data collection (e.g., collection of genomic information). While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has carveouts for manufacture of drugs for supply under Medicaid and Medicare Part B, subject to the Secretary of Veteran Affairs' discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. If WuXi Biologics becomes subject to trade restrictions, sanctions, increased tariffs or other regulatory requirements by the U.S. government (including designation as a "biotechnology company of concern" under the U.S. BIOSECURE Act), or if the U.S. or Chinese government take retaliatory actions due to recent or increased tensions between the U.S. and China, it may have the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain "biotechnology companies of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We do business with companies in China and it is possible some of our contractual counterparties could be impacted by the legislation described above.

If our contract manufacturers cannot successfully manufacture our product candidates or products that conform to our specifications and the strict regulatory requirements of the FDA or similar regulatory authorities, they will not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities for the manufacture of our products. 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 or a similar regulatory authority does not approve these facilities for the manufacture of our products or 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 products or product candidates, if approved.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our products and product candidates. Any significant delay or discontinuation in the supply of such materials would delay commercialization and the 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 products and product candidates, 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 products or product candidates for commercial sale and/or our clinical studies. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Although we generally do not begin a clinical study unless we believe we have on hand, or will be able to manufacture, a sufficient supply of a product candidate to complete such study, and we currently envision that VISEN, which relies on us for clinical supply of our product candidates, as well as Teijin, which we currently contemplate will rely on us for future clinical and commercial supplies of our product candidates, would do the same, any significant delay or discontinuity in the supply of a product candidate, or the raw material components thereof, for a clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our, VISEN's or Teijin's clinical studies, product testing, and potential regulatory approval of our product candidates, which could harm our business and results of operations.

Any inability to obtain suppliers, including an inability to obtain, or delay in obtaining, approval of a supplier from the FDA or other regulatory authorities, would delay or prevent the clinical development and commercialization of our products and product candidates.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products and 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 products and product candidates. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts.

Product liability claims may be expensive to defend and may result in judgements against us which are potentially punitive. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products and product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products and 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 products or 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 commercial sales and use in our clinical trials in the amount of $20 million in the aggregate on our primary insurance policy and $100 million in the aggregate on our excess insurance policy. Any claim that may be brought against us could result in a court judgement or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various limits, exclusions and deductibles, and given these various limits, exclusions and deductibles, we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms.

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

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

- expand our general and administrative functions;
- identify, recruit, screen, 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, compliance and management controls, reporting systems and procedures.

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

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

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

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 ("Section 404"), and the related rules of the SEC, which generally require our senior management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting, and we are required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting.

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

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

Our 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 product candidates;
- the amount and timing of revenue from product sales;
- the potential market opportunities and patient populations for our products and product candidates;
- the initiation of intellectual property litigation by third-parties or by us;
- the amount and timing of operating costs and capital expenditures relating to the expansion of our business operations and facilities;
- the timing of the commencement, completion or termination of collaboration agreements;
- the timing and amount of payments to us under collaboration agreements, if any;
- the introduction of new products and services by us, collaboration partners or our competitors;
- delays in preclinical testing and clinical studies;
- changes in regulatory requirements for clinical studies;

- costs and expenses associated with preclinical testing and clinical studies;
- exchange rate fluctuations;
- the regional and global effect of inflation;
- the adverse impact of multiple interest rate increases implemented by the U.S. Federal Reserve; and
- payment of license fees for the right to use third-party proprietary rights, if any.

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

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

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

- up-front, milestone and royalty payments, equity investments and financial support of new research and development candidates including increase of personnel, all of which may be substantial;
- exposure to unknown liabilities, including potential indemnification claims from a potential spin-off or out-license of certain of our intellectual property rights;
- disruption of our business and diversion of our management's time and attention to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher-than-expected acquisition and integration costs;
- lower-than-expected benefits, from out-licensing or selling our technology, intellectual property or any of our subsidiaries or, from in-licensing intellectual property or purchasing assets;
- write-downs of assets or goodwill or impairment charges;
- difficulty and cost in combining or separating the operations and personnel of any acquired or sold businesses with our existing operations and personnel;
- we may disagree with our strategic partners about decisions affecting the business, which could result in litigation or arbitration that increases our expenses, distracts our officers and directors and disrupts the day-to-day operations of the strategic venture, including by delaying important decisions until the dispute is resolved;
- our strategic partners may take actions that we oppose;
- our strategic partners might experience financial distress or become bankrupt;
- 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.

In addition, to the extent we enter into a strategic transaction that includes ongoing operations or shared ownership and management, our strategic partners may take actions that we oppose or we may disagree with our strategic partners about decisions affecting the business, which could result in litigation or arbitration, distract our officers and directors and otherwise disrupt the day-to-day operations of our business and the business of the strategic partner or entity. Furthermore, to the extent that our directors and officers serve on the boards of our strategic partners, such directors may be required to abstain from board decision-making in the event of a conflict of interest.

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.

The Royalty Pharma Agreements place restrictions on our operating and financial flexibility, and if we fail to comply with certain covenants in the Royalty Pharma Agreements, our results of operations and financial condition may be harmed.

In September 2023 and September 2024, we entered into the Royalty Pharma Agreements. The Royalty Pharma Agreements contain covenants that impose on us certain obligations with respect to payment, diligence, reporting, intellectual property, in-licenses, out-licenses and certain other actions, as well as indemnification obligations. Among other things, these covenants require us to use commercially reasonable efforts to manufacture and commercialize YORVIPATH and SKYTROFA in the United States and to develop SKYTROFA for a new indication, and limit our ability to create or incur liens or dispose of certain assets related to YORVIPATH and SKYTROFA. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might otherwise be advantageous to us and our stockholders. Pursuant to the Royalty Pharma Agreements, we have granted to Royalty Pharma back-up security interest in certain assets to secure our obligations under the Royalty Pharma Agreements. If we are unable to comply with our obligations, Royalty Pharma may be entitled to take possession of such assets, which could have a material adverse effect on our business, financial condition and results of operations.

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

Due to the international scope of our operations, fluctuations in exchange rates, particularly between the Euro, the Danish Krone and the U.S. Dollar, may adversely affect us. Although we are based in Denmark, we source research and development, manufacturing, consulting and other services from several countries. Further, potential future revenue may be derived from abroad, including from the United States. We currently attempt to limit our exposure to exchange rate risks by maintaining cash positions in the currencies in which we expect to incur the majority of our future expenses; however, for a variety of reasons we may be unable to maintain cash positions in the currencies in which we expect to incur the majority of our future expenses and we may fail to predict the currency of our future expenses, accurately or at all. As a result, our business and the price of the ADSs may be affected by fluctuations in foreign exchange rates between the Euro and these other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period.

We currently do not enter into foreign exchange contracts to cover our exposure to exchange rate fluctuations, or any other form of exchange rate hedging arrangements. If we fail to manage foreign exchange risk adequately our business, results of operations and prospects, and the value of our shares or ADSs may be adversely affected.

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

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

Since the end of the Brexit transition period on January 1, 2021, Great Britain (England, Scotland and Wales) ("GB") has not been directly subject to EU laws, however between January 1, 2021 and December 31, 2024 and as a result of the Northern Ireland Protocol, different rules applied in Northern Ireland than in GB; broadly, Northern Ireland continued to follow the EU regulatory regime. On January 1, 2025, a new arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the UK's MHRA with respect to medicinal products. The Windsor Framework removed EU licensing processes and EU labelling and serialization requirements in relation to Northern Ireland and introduced a UK-wide licensing process for medicines. In addition, new legislation such as the EU CTR is not applicable in GB. While the EU-UK Trade and Cooperation Agreement includes the mutual recognition of Good Manufacturing Practice ("GMP"), it does not contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards. There may be divergent local requirements in GB from the EU in the future, which may impact clinical and development activities that occur in the UK in the future. Similarly, clinical trial submissions in the UK will not be able to be bundled with those of EU member states within the EMA Clinical Trial Information System, adding further complexity, cost and potential risk to future clinical and development activity in the UK. Significant political and economic uncertainty remains about how much the relationship between the UK and EU will differ as a result of the UK's withdrawal.

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

Risks associated with our international operations, including seeking and obtaining approval to commercialize our product candidates in jurisdictions outside the U.S. and EU, 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 and device approvals in foreign countries;
- differing drug import and export rules;
- lacking or reduced protection for intellectual property rights in foreign countries;
- changes in laws or policies governing the terms of foreign trade, and in particular increased trade restrictions, tariffs or taxes on imports or exports from or to countries where we manufacture or sell, or our partners sell, our products and product candidates;
- different reimbursement systems, and different competitive drugs;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from work conducted by distributors;

- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the Foreign Corrupt Practices Act, its books and records provisions, or its anti-bribery provisions; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

For example, we originally planned to conduct the Phase 3 foresiGHt trial utilizing sites in Belarus and Russia, but instead we engaged alternative sites for the study following the outbreak of conflict in Ukraine, which adversely affected patient enrollment. In addition, the manufacture of our products and product candidates is dependent upon third-party manufacturers that are based in other parts of the world, including the United States, Europe (including the UK and Switzerland), Japan and China. This manufacturing process requires that the components used in our products and 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 product and other components of our products and product candidates are currently acquired from certain single-source suppliers. The loss of these suppliers, or their failure to supply could materially and adversely affect our business.

TransCon hGH drug product in vials is manufactured for use in clinical trials by Vetter Pharma Fertigung ("Vetter"), pursuant to our agreement with Vetter. TransCon hGH drug product in dual chamber cartridges for commercial and clinical use is supplied by Vetter for use in our drug delivery device made by Phillips Medisize A/S (formerly Medicom Innovation Partner A/S). The intermediates of our proprietary TransCon linkers are made by CARBOGEN AMCIS AG under an agreement with CARBOGEN AMCIS AG and accompanying purchase orders. For products that utilize soluble TransCon carriers, NOF Corporation (Japan) ("NOF"), supplies PEGs. Furthermore, NOF is responsible for coupling the TransCon linker used for TransCon hGH to methoxy PEG, under manufacturing agreements and accompanying purchase orders. Our growth hormone parent drug as well as our TransCon hGH drug substance are supplied by both Fujifilm Diosynth Biotechnologies UK Limited ("Fujifilm"), and Lonza Ltd. Our PTH as well as our TransCon PTH drug substance is supplied by Bachem, Switzerland, pursuant to our agreement with Bachem. Vetter manufactures the TransCon PTH drug product in cartridges and assembles the cartridges with a drug delivery device made by Ypsomed AG. CNP drug substance is supplied by Wacker Biotech, Germany. Our TransCon CNP drug product in vials is manufactured by Vetter pursuant to our agreement with Vetter. We do not currently have any other suppliers for the drug substance, drug product or other components of our TransCon hGH, TransCon PTH and TransCon CNP, although we believe that there are alternate sources of supply that could satisfy our clinical and commercial requirements, we cannot provide assurance that identifying alternate sources and establishing relationships with such sources would not result in significant delays in the commercialization or development of our products and 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 commercialization or development of our products or 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 technologies.

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

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

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

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

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

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

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

We are highly dependent on the principal members of our executive management and scientific staff, the loss of whose services could adversely affect the achievement of planned development objectives. In addition, we could experience difficulties attracting and retaining qualified employees in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

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

Our information technology systems, or those of our CROs or other contractors or consultants, may fail or suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity, which could result in a material disruption of our product development programs and other critical business functions.

In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information, preclinical and clinical trial data, and personal information (collectively, "Confidential Information"). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information.

Despite the implementation of security measures, our information technology systems and those of our CROs and other contractors and consultants are vulnerable to attack and damage from computer viruses and malware (e.g., ransomware), unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures, malfeasance by external or internal parties, human error (e.g., social engineering, phishing). Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques – including artificial intelligence – that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. If we or our third-party vendors were to experience a significant cybersecurity breach of our or their information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counterparties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including data loss or the loss of or damage to intellectual property or other proprietary information. There can also be no assurance that our and our third-party service providers', strategic partners', contractors', consultants', CROs' and collaborators' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

We and certain of our service providers may from time to time be subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our and our critical third parties' operations, it could result in a material disruption of our programs, our operations, and ultimately, our financial results. For example, the loss of clinical trial data from completed or ongoing clinical trials for our products or 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 products or product candidates could be delayed.

If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to applicable privacy and security laws. Any security compromise affecting us, our service providers, strategic partners, other contractors, consultants, or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development and commercialization of our products and services could be delayed. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our business. Furthermore, federal, state and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. Laws around cybersecurity are also developing, and changes in such laws may require additional compliance costs. For example, in the EU, more stringent rules around cybersecurity are being adopted, such as the NIS2 Directive, which requires in-scope entities to implement heightened cybersecurity measures and responses, including with respect to security incident handling and reporting obligations. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Our business has been, and may continue to be, adversely affected by health epidemics, pandemics and other outbreaks of infectious disease.

Public health threats, such as influenza and other highly communicable diseases or viruses, outbreaks of which have from time to time occurred in various parts of the world in which we operate, could adversely impact our operations, as well as the operations of our partners and our and their respective vendors, suppliers and other business partners. Any of these public health threats and related consequences could adversely affect our financial results.

The potential future measures put in place as a result of any future epidemic, pandemic, or health crisis could cause disruptions that could severely impact our business, clinical trials and commercialization activities, including by causing delays to our clinical trials, interrupting our supply chain, restricting access to our facilities, placing restrictions on our workforce and the workforce of our partners, or delaying interactions with regulators.

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

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

Unfavorable global and regional economic, political, health, climate and other conditions and events could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by global or regional economic, political, health, climate and other conditions and events. A global financial crisis or global or regional political and economic instability, failure of banks, wars, terrorism, civil unrest, outbreaks of disease, and other unexpected events, such as natural disasters, internet security threats, and damage to global communication networks, could cause extreme volatility, disrupt our business and increase our costs and expenses. Business disruptions could include, among others, disruptions to clinical enrollment, clinical site availability, patient accessibility, conduct of our clinical trials and commercialization activities, as well as temporary closures of our facilities and the facilities of suppliers or manufacturers in our supply chain.

For example, trade policies and geopolitical disputes (including as a result of China-Taiwan geo-political instability) and other international conflicts can result in tariffs, sanctions and other measures that restrict international trade, and can materially adversely affect our business, particularly if these measures occur in regions where our third-party contract manufacturers operate. Countries may also adopt measures, such as controls on imports or exports of goods, technology or data, that could adversely impact our operations and supply chain. These geopolitical risks could also adversely affect VISEN's activities in China.

In addition, global credit and financial markets have experienced volatility and disruptions over the past years, including concerns about declines in consumer confidence, declines in economic growth, increases in the rate of inflation, increases in borrowing rates and changes in liquidity and credit availability, and uncertainty about economic stability, including most recently in connection with actions undertaken by the U.S. Federal Reserve Board to address inflation.

The military conflict between Russia and Ukraine has increased the likelihood of supply interruptions and made it difficult to conduct business operations, including clinical trials, in the region and in nearby countries. We originally planned to conduct the Phase 3 foresiGHt trial utilizing sites in Belarus and Russia, but instead we engaged with alternative sites for the study following the outbreak of conflict in Ukraine, which adversely affected patient enrollment. Such developments could negatively impact such operations or require use to delay or suspend clinical trial activities, which may increase product development costs and harm our business.

Separately, on October 7, 2023, Hamas, an organization designated by the U.S. as a terrorist organization, launched a series of coordinated attacks from the Gaza Strip onto Israel. On October 8, 2023, Israel formally declared war on Hamas, and the armed conflict is ongoing as of the date of this filing. Hostilities between Israel and Hamas could escalate and involve surrounding countries in the Middle East. To date, we have not experienced any material interruptions in our infrastructure, supplies, technology systems, or networks needed to support our operations as a result of the conflict between Israel and Hamas.

We have no way to predict the progress, outcome or consequences of the military conflict in Ukraine or its impacts in Ukraine, Russia, Belarus, Europe, or the U.S, or of the conflict in the Israel-Gaza regions and any potential increases in hostilities in the Middle East. The length, impact, and outcome of ongoing military conflicts is highly unpredictable and could lead to significant market and other disruptions, including significant volatility in commodity prices and supply of energy resources, instability in financial markets, supply chain interruptions, political and social instability, trade disputes or trade barriers, changes in consumer or purchaser preferences, as well as an increase in cyberattacks and espionage.

Similarly, global climate change could result in certain types of natural disasters occurring more frequently or with more intense effects. Some of our corporate and operational functions are located in California, which has experienced severe earthquakes, droughts, fires and other natural disasters in the past. We do not have multiple-site capacity for all of our operations in the event of a business disruption. Furthermore, parties in our supply chain and our customers are similarly vulnerable to these global or regional economic, political, health, climate and other conditions and events. Global or regional economic, political, health, climate and other conditions and events could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which such conditions and events could adversely impact our business.

Risks Related to Government Regulatory and Legal Requirements

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

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA, EU legislative bodies and other regulatory authorities in the United States, the EU and other jurisdictions, which regulations differ from country to country. We are not permitted to market any drug product in the United States until we receive marketing approval from the FDA. Equally, we are not permitted to market any drug product in the EU until we receive a marketing authorization from the EC or EU member state competent authorities.

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

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

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

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

- the EMA, the FDA or other comparable foreign regulatory authorities may disagree with the design or implementation of our, or any collaboration partners', clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which approval is sought;
- the EMA, the FDA or comparable foreign regulatory authorities may disagree with the interpretation of data from preclinical studies or clinical studies;
- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of an NDA or BLA, MAA, or other submission or to obtain regulatory approval in the United States, the EU or elsewhere;
- we, or any collaboration partners, may be unable to demonstrate to the EMA, the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the 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 FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, FDA and foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the EC in November 2020.

The EC's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council of the EU and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

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

In addition, even if we ultimately obtain approval for any product candidate, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, may impose a REMS or similar risk management measures, 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.

Additional time may be required to obtain marketing authorizations for any of our product candidates that we develop as combination products.

On August 9, 2024, the FDA approved YORVIPATH for the treatment of hypoparathyroidism in adults. The approved presentation for YORVIPATH includes a pen-injector device we developed with Ypsomed to facilitate patient administration of TransCon PTH. As such, the pen-injector version of TransCon PTH is regulated as a combination product by the FDA and other regulatory authorities. Combination products require coordination within the FDA and within comparable regulatory agencies for review of their drug and device components. The EU regulates medical devices and medicinal products separately, through different legislative instruments, and the applicable requirements will vary depending on the type of drug-device combination product. For instance, drug-delivery products intended to administer a medicinal product where the medicinal product and the device form a single integral product are regulated as medicinal products in the EU. In such a case, the MAA must include – where available – the results of the assessment of the conformity of the device part with the EU Medical Devices Regulation ("EU MDR") contained in the manufacturer's EU declaration of conformity of the device or the relevant certificate issued by a notified body. If the MAA does not include the results of the conformity assessment and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required, the EMA or the EU member state competent authority must require the applicant to provide a notified body opinion on the conformity of the device. By contrast, in case of drug-delivery products intended to administer a medicinal product where the device and the medicinal product do not form a single integral product (but are, e.g., co-packaged), the medicinal product is regulated in accordance with the rules for medicinal products described above while the device part is regulated as a medical device and will have to comply with all the requirements set forth by the EU MDR.

Although the FDA and comparable foreign agencies have or may have systems in place for the review and approval of combination products, we may experience additional delays in the development and commercialization of such product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Moreover, although we anticipate that the device component of any combination product candidates we develop will be reviewed within the usual time frames expected for the underlying drug component application, and that no separate marketing application for the device components of such product candidates will be required in the United States, the FDA or comparable regulatory authorities may delay approval or require additional studies with the device which may delay the approval of the combination product.

For example, in April 2023 the FDA issued a Complete Response Letter in response to our original NDA submission for TransCon PTH, in which the FDA cited concerns related to the manufacturing control strategy for variability of delivered dose in the TransCon PTH drug/device combination product. Although the FDA subsequently approved our NDA for YORVIPATH, there is no guarantee that we will not encounter similar challenges or delays with respect to any other combination-product development programs we may pursue.

Even after a regulatory approval for a product candidate, we are subject to ongoing regulatory obligations and review, which may result in significant additional expenses. Additionally, our products and 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, including YORVIPATH and SKYTROFA in the U.S. and EU, and our other product candidates extend 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 the United States, the EU and authorities in other territories. Following any regulatory approval of a product candidate, we, any collaboration partners and the manufacturers of our products will be subject to continuing regulatory obligations, including safety reporting requirements, regulatory oversight of product promotion and marketing, and cGMP or similar requirements. Furthermore, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These regulations cover all aspects of manufacturing, testing, quality control and recordkeeping of our products. If we or any collaboration partners or manufacturers fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs or similar requirements 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 addition, under the Federal Food, Drug, and Cosmetic Act, particular restrictions are placed on the distribution of human growth hormone products, including TransCon hGH. The distribution of product samples to physicians must also comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities for our products remain subject to periodic inspection by regulatory authorities and must continue to adhere to International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the FDA's cGMP requirements. Application holders must obtain FDA approval for many product and manufacturing changes, depending on the nature of the change. Sales, marketing, and scientific/educational grant programs must comply with the U.S. Anti-Kickback Statute, the False Claims Act, as amended and similar state laws. Certain payments and other transfers of value to U.S. licensed physicians (as defined under statute) and teaching hospitals must be reported under the Physician Payments Sunshine Act. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to U.S. consumer protection and unfair competition laws. For further discussion of these laws, see "Risk Factors—*We are subject to healthcare laws, regulation and enforcement; our failure to comply with these laws could harm our results of operations and financial conditions.*"

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

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

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

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

In addition, the FDA's and foreign regulatory authorities' policies may change and additional government laws or regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Within the EU, once a marketing authorization is obtained, numerous post-approval requirements similar to the above ones also apply, and as in the United States, advertising and promotional activities for the product must be consistent with the approved summary of product characteristics and therefore off-label promotion of medicinal products is not permitted. Furthermore, the advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. The requirements are regulated by both EU regulations as well as national applicable regulations.

The regulatory requirements relating to the manufacturing, testing, marketing and sale of pharmaceutical products are subject to periodic change. This may impact our development plans. Changes in the regulations governing us could increase costs and adversely affect our business.

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

Disruptions at the FDA and other government agencies caused by funding shortages or staffing limitations could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs, and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if funding shortages, staffing limitations or similar factors hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other activities, such events could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 in the United States are essential for most patients to be able to afford treatments including our products and product candidates, if approved. 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 our products, and potentially attract additional collaboration partners to invest in the development of our product candidates. We cannot be sure that adequate coverage and reimbursement in the United States, the EU or elsewhere will be available for our products or any products that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Third-party payors increasingly are challenging prices charged for pharmaceutical products, medical devices and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug is available. It is possible that a third-party payor may consider our products or product candidates, if approved, and the generic or biosimilar 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 products or product candidates, if approved, pricing of the existing parent drug may limit the amount we will be able to charge for such product. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products or product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs, biologics and medical devices will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs, biologics and medical devices. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products or 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 products and product candidates, if approved, and on related parent drugs. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Many countries, including the EU member states, established complex and lengthy procedures to obtain price approvals, coverage and reimbursement. These procedures vary from country to country but are commonly initiated after grant of the related marketing authorization. More particularly, in the EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced countries. Reductions in the pricing of our medicinal products in one EU member state could affect the price in other EU member states and, thus, have a negative impact on our financial results. 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 products or product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. As an example, many EU member states review periodically their decisions concerning the pricing and reimbursement of medicinal products. The outcome of these reviews cannot be predicted and could have adverse effects on the pricing and reimbursement of our medicinal products in the EU member states.

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

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

We depend on third-parties to manufacture products employing our TransCon technologies. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP or similar requirements outside the United States. 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 our products and product candidates for clinical studies or commercial sale, including our existing contract manufacturers for our products and product candidates, are subject to extensive regulation. Manufacturing facilities are subject to pre-approval and ongoing periodic inspection by the FDA and other corresponding governmental authorities, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing of products employing our TransCon technologies. After regulatory approvals or licensure are obtained, the subsequent discovery of previously unknown manufacturing, quality control or regulatory documentation problems or failure to maintain compliance with the regulatory requirements may result in restrictions on the marketing of a product, revocation of the license, withdrawal of the product from the market, seizures, injunctions, or criminal sanctions. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA, BLA, MAA or comparable regulatory filing on a timely basis and must adhere to cGMP or similar regulations enforced by the FDA and other regulatory authorities through their facilities inspection programs. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel.

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

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

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through submission and subsequent approval of a supplemental NDA or BLA, a marketing authorization variation application or equivalent foreign regulatory filing, which could result in further delay. The regulatory authorities may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. Furthermore, interruption or delay in supplies from one contract manufacturer may cause delays further down the supply chain, as certain contract manufacturers may rely on delivery of materials from other contract manufacturers.

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

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

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

Our ability to effectively monitor and respond to the rapid and ongoing developments and expectations relating to environmental, social and governance matters, including related social expectations and concerns, may impose unexpected costs on us or result in reputational or other harm to us that could have a material adverse effect on our business, financial condition and results of operations.

There is an increasing focus and rapid and ongoing developments and changing expectations from certain investors, customers, consumers, employees and other stakeholders concerning environmental, social and corporate governance ("ESG") matters. Additionally, public interest and legislative pressure related to public companies' ESG practices continue to grow, which may result in increased regulatory, social or other scrutiny on us.

In the past, we have undertaken, and in future may undertake, various initiatives to improve our ESG profile or respond to stakeholder expectations; however, such initiatives entail costs and may not have the desired effect. For example, many initiatives rely on methodologies, standards, or data that are complex and evolving. Our approach to such matters also evolves, and there can be no guarantee that our approach will align with the expectations of any particular stakeholder. Stakeholder expectations vary, and in some circumstances conflict. For example, various policymakers, such as the EU and State of California, have adopted requirements for certain disclosures or other actions on climate and related ESG matters. Such requirements are not uniform, and may not be interpreted or applied uniformly, which can increase the cost and complexity of compliance, along with any other risks. Simultaneously, other stakeholders (including some policymakers) have sought to constrain companies attention to certain ESG matters.

Our failure or perceived failure to meet the standards set by various constituencies, or to successfully navigate competing expectations, could damage our reputation and our relationships with investors, governments, customers, employees, third parties and the communities in which we operate and expose us to increased regulatory risk, put us at a commercial disadvantage relative to our peers and materially adversely affect our business, financial condition, results of operations, ability to participate in debt and equity markets and the value of our shares or ADSs. Various of our suppliers, business partners, or other stakeholders are subject to similar expectations, which may augment or create additional risks.

If we fail to comply or are found to have failed to comply with EU, FDA and other local 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 FDA and other regulatory authorities, as well as courts. For example, we are restricted from marketing YORVIPATH and SKYTROFA and any other product candidate that receives marketing approval outside of its approved labeling, also referred to as off-label promotion. However, physicians may nevertheless lawfully prescribe an approved product to their patients in a manner that is inconsistent with the approved label, which is an off-label use. The FDA or other government authorities may allege or find that our practices constitute prohibited promotion for unapproved uses.

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

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

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

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

We are subject to global anti-corruption laws, including but not limited to the U.S. Foreign Corrupt Practices Act, and non-compliance with such laws can subject us to criminal or civil liability and harm our business, financial condition and results of operations.

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

There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these requirements. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from allegations, governmental investigations or other actions or lawsuits stemming from a failure to comply with these requirements.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including civil or criminal fines and penalties, disgorgement of profits, injunctions and debarment from government contracts, as well as related stockholder lawsuits and other remedial measures, all of which could adversely affect our reputation, business, financial condition and results of operations. Investigations of alleged violations can also be disruptive and cause us to incur significant legal and investigatory fees.

Our failure to comply with trade compliance and economic sanctions laws and regulations of the United States and applicable international jurisdictions could materially adversely affect our reputation and results of operations.

Our business must be conducted in compliance with applicable economic and trade sanctions laws and regulations, such as those administered and enforced by the U.S. Department of Treasury's Office of Foreign Assets Control, the U.S. Department of State, the U.S. Department of Commerce, the United Nations Security Council and other relevant sanctions authorities. Our global operations expose us to the risk of violating, or being accused of violating, economic and trade sanctions laws and regulations. Our failure to comply with these laws and regulations may expose us to reputational harm as well as significant penalties, including criminal fines, imprisonment, civil fines, disgorgement of profits, injunctions and debarment from government contracts, as well as other remedial measures. Investigations of alleged violations can be expensive and disruptive. Despite our compliance efforts and activities we cannot assure compliance by our employees or representatives for which we may be held responsible, and any such violation could materially adversely affect our reputation, business, financial condition and results of operations.

Regulations related to "conflict minerals" may cause us to incur additional expenses and could limit the supply and increase the cost of certain metals used in manufacturing our products.

In August 2012, the SEC adopted a rule requiring disclosures of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured by U.S.-listed companies. The conflict minerals rule requires companies annually to diligence, disclose and report whether or not such minerals originate from the Democratic Republic of Congo and/or adjoining countries of Angola, Burundi, Central African Republic, the Republic of the Congo, Rwanda, South Sudan, Tanzania, Uganda, and Zambia. The rule could affect sourcing at competitive prices and availability in sufficient quantities of certain minerals, including gold and tin, which are necessary to the functionality of our products, including our TransCon hGH auto-injector. The number of suppliers who provide conflict-free minerals may be limited. In addition, there may be material costs associated with complying with the disclosure requirements, such as costs related to determining the source of certain minerals used in our products, as well as costs of possible changes to products, processes, or sources of supply as a consequence of such verification activities. Due to the depth and complexity of the supply chain, we may not be able to sufficiently verify the origins of the relevant minerals used in our products through the due diligence procedures that we implement or the information that we receive from our suppliers may be inaccurate or inadequate, which may harm our reputation or subject us to SEC enforcement risks. In addition, we may encounter challenges to satisfy those customers who require that all of the components of our products be certified as conflict-free, which could place us at a competitive disadvantage if we are unable to do so.

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

In order to market our products outside of the United States, we, or any potential partner, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our products. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed in these "Risk Factors", as well as other risks.

In the EU, medicinal products can only be commercialized after obtaining a marketing authorization. For additional information, see "Item 4 B. Information on the Company - Business Overview - Foreign Regulation."

Outside the U.S. and the EU, 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 EU approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA, EC, or EU member state 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, EC, or EU member states 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, EC, or EU member states 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 are subject to healthcare laws, regulation and enforcement; our failure to comply with these laws could harm our results of operations and financial conditions.

We are subject to 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 affect our ability to operate include:

- the U.S. Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under U.S. federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- U.S. false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- U.S. federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- U.S. federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows, or should know, it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the U.S. federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives) and teaching hospitals, and ownership and investment interests held by physicians (as defined under statute) and their immediate family members;
- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- state law equivalents of each of the above U.S. federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;
- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and
- analogous foreign laws and regulations, including restrictions imposed on the promotion and marketing of medicinal products in the EU member states and other countries, restrictions on interactions with healthcare professionals and requirements for public disclosure of payments made to physicians. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we may decide not to directly promote or market our products, inappropriate activity by our international distribution partners could have implications for us.

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

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

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs that we participate in, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Medicaid is a joint federal and state program administered by the states for low income and disabled beneficiaries. We participate in and have certain price reporting obligations under the Medicaid Drug Rebate Program ("MDRP"), as a condition of having covered outpatient drugs payable under Medicaid and, if applicable, under Medicare Part B. The MDRP requires us to pay a rebate to state Medicaid programs every quarter for each unit of our covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. The rebate is based on pricing data that we must report on a monthly and quarterly basis to the Centers for Medicare & Medicaid Services ("CMS"), the federal agency that administers the MDRP and other governmental healthcare programs. These data include the average manufacturer price ("AMP") for each drug and, in the case of innovator products, the best price, which in general represents the lowest price available from the manufacturer to certain entities in the United States in any pricing structure, calculated to include all sales and eligible rebates, discounts and other price concessions. The Medicaid rebate consists of two components, the basic rebate and the additional rebate, which is triggered if the AMP for a drug increases faster than inflation. If we become aware that our MDRP government price reporting submission for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information timely or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP. In the event that CMS terminates our rebate agreement pursuant to which we participate in the MDRP, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Our failure to comply with our MDRP price reporting and rebate payment obligations could negatively impact our financial results.

The IRA imposes rebates under Medicare Part B and Medicare Part D that are triggered by price increases that outpace inflation. The Medicare Part D rebate, if applicable, is calculated on the basis of the AMP figures we report pursuant to the MDRP.

Federal law requires that any company that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and, if applicable, Medicare Part B. We participate in the 340B program, which is administered by the Health Resources and Services Administration ("HRSA"), and requires us to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes those prices to 340B covered entities. In addition, HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized a revised regulation implementing an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs. Our failure to comply with 340B program requirements could negatively impact our financial results. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under legislation or regulation could affect our 340B ceiling price calculations and also negatively impact our financial results.

In order for our products to be paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we also participate in the U.S. Department of Veterans Affairs("VA"), Federal Supply Schedule ("FSS"), pricing program. As part of this program, we are required to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price ("FCP"), to four federal agencies (VA, U.S. Department of Defense ("DOD"), Public Health Service, and U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we must calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant civil monetary penalties for each item of false information. The FSS pricing and contracting obligations also contain extensive disclosure and certification requirements.

We also participate in the Tricare Retail Pharmacy program, under which we are required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our innovator products on a Tricare Agreement in order for them to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges could result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation. Requirements of pharmaceutical manufacturers under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. CMS, the Department of Health & Human Services Office of Inspector General, and other governmental agencies have pursued manufacturers that were alleged to have failed to report these data to the government in a timely or accurate manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that any submissions we are required to make under the MDRP, the 340B program, the VA/FSS program, the Tricare Retail Pharmacy Program, and other governmental drug pricing programs will not be found to be incomplete or incorrect.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

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

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

Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, California enacted the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the "CCPA"), requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information, (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information, and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may be required. Similar laws have passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Furthermore, the Federal Trade Commission ("FTC"), has authority to initiate enforcement actions against entities that make deceptive statements about privacy and data sharing in privacy policies, fail to limit third-party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5(a) of the FTC Act. Even when HIPAA or a state law does not apply, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair and/or deceptive acts or practices in violation of Section 5(a) of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Additionally, federal and state consumer protection laws are increasingly being applied by FTC and states' attorneys general to regulate the collection, use, storage, and disclosure of personal or personally identifiable information, through websites or otherwise, and to regulate the presentation of website content.

In 2024, the National Security Division of the U.S. Department of Justice (the "DOJ") issued a new rule – referred to as the "Data Security Program" ("DSP") – to implement Executive Order 14117 aimed at preventing access to "bulk U.S. sensitive personal data" and "government-related data" by "countries of concern" (including China, Russia, Iran, North Korea, Cuba, and Venezuela) and "covered persons" (as all such terms are defined in the DSP). Effective as of April 8, 2025, and fully enforceable as of July 9, 2025, the DSP imposes stringent obligations on companies within its scope and prohibits or restricts "covered data transactions" that grant countries of concern or covered persons access to bulk U.S. sensitive personal data or any amount of government-related data. The DSP is new, complex and has yet to be enforced, and as such, there is a risk that our interpretation of its applicability, scope, and requirements is incorrect, incomplete, or misapplied. Compliance with the DSP may require us to invest heavily in data security and compliance measures, such as implementing and complying with the Cybersecurity and Infrastructure Security Agency's guidelines and other burdensome recordkeeping, reporting, and auditing requirements. It may also require us to implement new processes, stop or restrict certain data transfers, alter the geographic scope of our operations, cease doing business with certain third parties or using certain tools or vendors, or change how data flows throughout our business, any of which could materially impact our business operations or hinder our ability to grow our business. Finally, non-compliance with the DSP could result in significant civil or criminal penalties, which could materially adversely affect our business, results of operations, and financial condition.

In Europe, the General Data Protection Regulation (the "EU GDPR") and in the United Kingdom the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (the "UK GDPR" and together with the EU GDPR, referred to as the "GDPR"), impose comprehensive data privacy compliance obligations in relation to our processing of personal data of individuals within the European Economic Area ("EEA"), including clinical trial data, or in the context of our activities within the EEA, including a principle of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit, as well as regulating cross-border transfers of personal data out of the EEA and the UK. If we do not comply with our obligations under the GDPR, we could be exposed to fines under both the EU GDPR and UK GDPR of up to the greater of €20 million/ GBP 17.5 million or up to 4% of our total global annual revenue in the event of a significant breach. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations and financial condition.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union ("CJEU"), states that reliance on the standard contractual clauses - a standard form of contract approved by the EC as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. In relation to such cross-border transfers of personal data, we expect the existing legal complexity and uncertainty regarding international personal data transfers to continue, and international transfers to the United States, China, and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes; we may have to implement alternative data transfer mechanisms under the GDPR and/or take additional compliance and operational measures; and/or it could otherwise affect the manner in which we operate our business, and could adversely affect our business, operations and financial condition.

Relatedly, from January 1, 2021, companies have had to comply with both the GDPR and the UK GDPR, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation and adversely affect our business and results of operations. Further, we cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients', and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. In addition, if our practices are not consistent, or viewed as not consistent, with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may also become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, criminal or civil sanctions, all of which may harm our business, financial condition and results of operations.

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

From time to time, legislation is drafted and introduced in U.S. Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business. Similar risks exist in foreign jurisdictions. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

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

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

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

Since its enactment, there have been judicial, executive and Congressional challenges to certain provisions of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted, including reductions in Medicare payments to providers, which went into effect on April 1, 2013 and will stay in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several types of providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability effective January 1, 2024. The rebate was previously capped at 100% of the average manufacturer price for a covered outpatient drug. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for our products.

Recently, there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Most recently, in August 2022, the Inflation Reduction Act of 2022 ("IRA"), was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services ("HHS"), to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Centers for Medicare & Medicaid Services ("CMS") published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs, which will first be effective in 2027, although the program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated, and the impact of the IRA on our business and the pharmaceutical industry cannot yet be fully determined.

Under the IRA manufacturer discount program that replaced the coverage gap discount program as of January 1, 2025, manufacturers must give a 10% discount on Part D drugs in the initial coverage phase, and a 20% discount on Part D drugs in the so-called "catastrophic phase" (the phase after the patient incurs costs above the initial phase out-of-pocket threshold, which is $2,000 beginning in 2025). The IRA allows the 10% and 20% discounts to be phased in over time for certain drugs for "specified manufacturers." The IRA manufacturer discounting program also increases financial obligations of Part D prescription drug plans with respect to beneficiaries in the catastrophic coverage phase. This may incentivize Part D prescription drug plans to seek greater price concessions from manufacturers in order to include their products on their formularies.

Most recently, the One Big Beautiful Bill Act ("OBBBA"), which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect the sales of YORVIPATH, SKYTROFA, and any other product candidate that we commercialize.

Additionally, the current administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how these proposals will be implemented, the policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for YORVIPATH and SKYTROFA. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the current administration is pursuing traditional regulatory pathways to impose drug pricing policies, although proposed regulations have not yet been published. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including through constraints on reimbursement, imposition of mandatory discounts, discounts, restrictions on access to certain products, transparency measures, and programs for importation from other countries or bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, while some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain for SKYTROFA or YORVIPATH or the frequency with which our products are prescribed or used. 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 products or 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, including TransCon hGH, 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.

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

In December 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA"), amending Directive 2011/24/EU, was adopted. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement. While the Regulation entered into force in January 2022, it entered into application on January 12, 2025, with preparatory and implementation-related steps taking place in the interim. The Regulation has a phased implementation depending on the concerned products. As a first step, these new rules started applying to MAAs for a new cancer medicinal products or an advanced therapy medicinal product ("ATMP") as of January 12, 2025. The rules will be extended to orphan medicinal products in January 2028 and will as of 2030 cover all new medicinal products.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in which we participate, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Medicaid is a joint federal and state program administered by the states for low income and disabled beneficiaries. We participate in and have certain price reporting obligations under the Medicaid Drug Rebate Program ("MDRP"), as a condition of having covered outpatient drugs payable under Medicaid and, if applicable, under Medicare Part B. The MDRP requires us to pay a rebate to state Medicaid programs every quarter for each unit of our covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. The rebate is based on pricing data that we must report on a monthly and quarterly basis to CMS, the federal agency that administers the MDRP and other governmental healthcare programs. These data include the average manufacturer price ("AMP") for each drug and, in the case of innovator products, the best price, which in general represents the lowest price available from the manufacturer to certain entities in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. The Medicaid rebate consists of two components, the basic rebate and the additional rebate, which is triggered if the AMP for a drug increases faster than inflation. If we become aware that our MDRP government price reporting submission for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information timely or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP. In the event that CMS terminates our rebate agreement pursuant to which we participate in the MDRP, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Our failure to comply with our MDRP price reporting and rebate payment obligations could negatively impact our financial results.

The recently-enacted IRA imposes rebates under Medicare Part B and Medicare Part D that are triggered by price increases that outpace inflation (first due in 2023), as described under the risk factor "*Legislative or regulatory healthcare reforms in the United States and in foreign jurisdictions may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates in the United States and in foreign jurisdictions and to produce, market and distribute our products in the United States and in foreign jurisdictions after clearance or approval is obtained*" above. The Medicare Part D rebate will be calculated on the basis of the AMP figures we report pursuant to the MDRP.

Federal law requires that any company that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and, if applicable, Medicare Part B. We participate in the 340B program, which is administered by the Health Resources and Services Administration ("HRSA"), and requires us to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The ACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts "orphan drugs," from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes those prices to 340B covered entities. In addition, HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized a revised regulation implementing an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs. Our failure to comply 340B program requirements could negatively impact our financial results. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under legislation or regulation could affect our 340B ceiling price calculations and also negatively impact our financial results.

In order for YORVIPATH, SKYTROFA, or any product candidates, if approved, to be paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we also participate in the U.S. Department of Veterans Affairs ("VA"), Federal Supply Schedule ("FSS"), pricing program. As part of this program, we are required to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price ("FCP"), to four federal agencies (VA, U.S. DOD, Public Health Service, and U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price ("Non-FAMP"), which we must calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant civil monetary penalties for each item of false information. The FSS pricing and contracting obligations also contain extensive disclosure and certification requirements.

We also participate in the Tricare Retail Pharmacy program, under which we are required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our innovator products on a Tricare Agreement in order for them to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges could result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation. Requirements of pharmaceutical manufacturers under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. CMS, the Department of Health & Human Services Office of Inspector General, and other governmental agencies have pursued manufacturers that were alleged to have failed to report these data to the government in a timely or accurate manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that any submissions we are required to make under the MDRP, the 340B program, the VA/FSS program, the Tricare Retail Pharmacy Program, and other governmental drug pricing programs will not be found to be incomplete or incorrect.

Risks Related to Our Intellectual Property

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

Our success depends in part on our ability to:

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

We will be able to protect our proprietary technologies from unauthorized use by third-parties only to the extent that such proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. Any non-confidential disclosure to or misappropriation by third-parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Where we elect to pursue patent protection on our proprietary technologies, we file, prosecute and maintain international and other national patent applications covering such technologies, including in the United States, Europe, China, and other jurisdictions. For additional information regarding our patents issued to us, see “Item 4 B. Information on the Company - Business Overview - Intellectual Property.” 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 or inventorship, 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 patent 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.

On June 1, 2023, the European Unitary Patent system and the European Unified Patent Court ("UPC"), were successfully launched, creating a single pan-European Unitary Patent and a new European patent court for litigation involving European patents. European patent applications now have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the UPC. In addition, conventional European patents, both already granted at the time the new system began and granted thereafter, are subject to the jurisdiction of the UPC, unless actively opted out. This is a significant change to European patent practice and deciding whether to opt-in or opt-out of Unitary Patent practice entail strategic and cost considerations. It will be several years before we will understand the scope of patent rights that are recognized and the strength of patent remedies that are provided by the UPC. While we have the right to opt our patents out of the UPC over the first seven years of the court's existence, doing so may preclude us from realizing the benefits of the UPC. We have opted our current European patents out of the UPC, but if we do not meet all of the formalities and requirements for opting our patents out of the UPC, our current or future European patents could remain under the jurisdiction of the UPC. The UPC provides our competitors with a new forum to centrally revoke our European patents, and allows for the possibility of a competitor to obtain pan-European injunctions. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries and our European patent applications, if issued, could be challenged in the UPC. Moreover, the decision whether to opt-in or opt-out of Unitary Patent status will require coordinating with co-applicants, if any, adding complexity to any such decision.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be highly uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other countries. Even if patents do issue on such patent applications, third-parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. For example, U.S. patents can be challenged by any person before the USPTO Patent Trial and Appeals Board at any time within the one-year period following that person's receipt of an allegation of infringement of the patents. Patents granted by the European Patent Office may be similarly opposed by any person within nine months from the publication of the grant. Similar proceedings are available in other jurisdictions, and in the United States, Europe and other jurisdictions third-parties can raise questions of validity with a patent office even before a patent has been 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 products or 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 products or product candidates is successfully challenged, then our ability to commercialize our products or product candidates could be negatively affected, and we may face unexpected competition that could harm our business. Further, patents have a limited lifespan and patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date excluding U.S. provisional patent applications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. If we encounter delays in our clinical trials, the period of time during which we could market our products or product candidates, if approved, under patent protection would be reduced. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

Moreover, geo-political actions in the U.S. and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the U.S. and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the U.S. and other "unfriendly states" designated by Russia without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or our in-licensed issued patents may not encompass commercially viable products or product candidates, 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 the scope may be narrowed; 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 products or product candidates, our ability to develop and commercialize our products or product candidates could be harmed and we might not be able to prevent competitors from making, using, selling, importing or otherwise exploiting competing products or product candidates. This failure to properly protect the intellectual property rights relating to our products or product candidates could harm our business, financial condition and operating results. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how on their own without relying on our proprietary technologies or information.

Even where laws provide protection, litigation or any other dispute resolution proceedings necessary to enforce and determine the scope of our proprietary rights may be costly and time-consuming, and the outcome of such litigation or dispute resolution proceedings would be uncertain. If we were to initiate legal proceedings against a third-party to enforce a patent covering one of our products or product candidates, 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 our products or product candidates, we would lose at least part, and perhaps all, of the patent protection on such product or product candidate. Such a loss of patent protection would harm our business. Moreover, our competitors could counterclaim in any suit to enforce our patents that we infringe their intellectual property. Furthermore, some of our competitors have substantially greater intellectual property portfolios, and resources, than we do.

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

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

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

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

Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

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

In addition to patents, we rely on trade secrets and proprietary know-how. We seek protection, in part, through confidentiality and proprietary information clauses in agreements with our collaboration partners, employees, consultants, outside scientific collaboration partners and sponsored researchers and other advisors. Although we generally require all of our employees, consultants, advisors and any third-parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, and endeavor to execute confidentiality agreements with all such parties, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property or who had access to our proprietary information, nor can we be certain that our agreements with such parties will not be breached. These agreements may not effectively prevent disclosure of confidential and proprietary information and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential and proprietary information. We cannot guarantee that our trade secrets and other confidential proprietary information will not be publicly disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. We may need to share our proprietary information, including trade secrets, with our current and future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. The failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

If we are sued for allegedly infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in such 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, products or product candidates may be found to 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 products and product candidates. Additionally, we are aware of patents owned by BioMarin that are related to CNP variants. In particular, BioMarin owns a patent in Europe relating to CNP variants, and filed a case before the UPC related to alleged infringement against the patent. We filed an opposition in September 2022, and on October 16, 2025, the European Patent Office ("EPO") Technical Boards of Appeal revoked the patent. As a consequence of the revocation, the UPC dismissed the infringement case on December 29, 2025. On June 12, 2025, BioMarin also submitted a Citizen Petition to the FDA under Section 505(q) of the Federal Food, Drug and Cosmetic Act requesting that FDA refrain from approving any analog of human CNP as a treatment for achondroplasia until orphan-drug exclusivities applicable to VOXZOGO expire. We submitted a response to the FDA in September 2025 and do not believe that our pending NDA for TransCon CNP (navepegritide) should be impacted by the Citizen Petition. There is a risk that BioMarin will allege patent infringement in other jurisdictions and before other courts. Furthermore, BioMarin also owns a re-issue patent in the U.S. relating to CNP variants, and BioMarin has filed a complaint with the U.S. International Trade Commission related to alleged infringement of the re-issue patent, with a trial date set for April 2026. Although we believe that this patent is not infringed by us and/or is invalid, it is possible that a court or other form of tribunal would come to a different conclusion. For further details, please refer to "Item 4B. Information on the Company – Business Overview – TransCon Technologies– Achondroplasia." We thus cannot be certain that our technologies, products and product candidates will not be found to infringe these or other existing or future patents of third-parties. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products.

Additionally, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use, import or sale of our technologies, products or product candidates. We may not be aware of patents that have already been issued that a third-party might assert are infringed by our technologies, products or product candidates.

It is also possible that patents of which we are aware, but which we do not believe are relevant to our technologies, products or product candidates, could nevertheless be found to be infringed by our products or product candidates.

Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect.

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

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

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

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

Litigation may be necessary to:

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

Competitors may infringe our intellectual property. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings and some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent or other intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly, or amended such that they do not cover our product candidates. Moreover, such adverse determinations could put our patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our products or 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 and scientific personnel. 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 this kind of proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for the ADSs could be significantly harmed.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act ("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 filed after March 16, 2013, 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 Leahy-Smith Act could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technologies or our ability to enforce our proprietary technologies.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Since June 1, 2023, European patent applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. For additional information, see "If our intellectual property related to our products and product candidates is not adequate, we may not be able to compete effectively in our market."

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

As of December 31, 2025, over 100 of our employees work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees are generally subject to the provisions of the German Act on Employees' Inventions, which regulates the ownership of, and compensation for, inventions made by employees. Under this act, we face the risk that we may be required to pay additional compensation for assigned patent rights and disputes can occur between us and our employees or ex-employees pertaining to alleged non-adherence to the provisions of this act that may be costly to defend and consume our management's time and efforts whether we prevail or fail in such dispute. In addition, under the German Act on Employees' Inventions, certain employees may have retained rights to patents they invented or co-invented before October 2009. Although substantially all of these employees have assigned their interest in these patents to us, to the extent permitted by law, there is a risk that the compensation we provided to them may be deemed to be insufficient and we may be required under German law to increase the compensation due to such employees for the use of the patents. In those cases, where employees have not assigned their interests to us, we may need to pay compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, our results of operations could be adversely affected.

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

The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Public health pandemics, geopolitical instability, natural disasters, or similar events may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our product candidates. There could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government. Losing our patent rights could enable competitors to enter the market earlier than would otherwise have been the case.

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

We use various trademark rights in our business, including, Ascendis, Ascendis Pharma, TransCon, YORVIPATH and SKYTROFA. Trademark applications for TransCon hGH, TransCon PTH and TransCon CNP have been filed in the U.S. as well as the EU and other countries across the globe. However, our current or future trademarks and trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks, and we may not be able to obtain trademark protection in other territories that we consider of significant importance to us. Furthermore, other than for TransCon hGH, TransCon PTH and TransCon CNP, we have not yet registered for a commercial trade name for any other of our product candidates in the United States or elsewhere. During trademark registration proceedings, our trademark applications may be rejected. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third-parties can oppose pending trademark applications and seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings.

In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing our products under new brands. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third-parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

The FDA has approved the use of SKYTROFA for TransCon hGH and YORVIPATH for TransCon PTH in the United States; however, any name we propose to use with TransCon CNP, or our other product candidates in the United States or any other country must be approved by the FDA, EMA/EC or any other relevant health authority regardless of whether we have registered it, or applied to register it, as a trademark. For example, the FDA has approved the use of YORVIPATH and SKYTROFA for certain indications in the United States and the EC has granted marketing authorizations for YORVIPATH and SKYTROFA in the EU. The FDA as well as EMA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA, EMA or any other relevant approval authority objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third-parties and be acceptable to the FDA, EMA or any other relevant approval authority.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on our products or product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. For example, patents with claims directed to dry pharmaceutical formulations of TransCon hGH have issued in the United States, Europe, and other jurisdictions, but related claims were rejected in China, and our subsequent appeals were unsuccessful. As a result, our patent protection for TransCon hGH may expire sooner in China than in other jurisdictions. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and certain developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights in such countries. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third-parties. Consequently, we may not be able to prevent third-parties from practicing our inventions in certain countries outside the United States and many countries in Europe.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and product candidates 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 and product candidates 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 and product candidates. 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 have wrongfully hired an employee from a competitor or that we or these employees, consultants and contractors have used or disclosed such third-party intellectual property, including know-how, trade secrets or other proprietary information.

Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or access to consultants and contractors. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

We or our licensors may have relied on third-party consultants or collaborators or on funds from third-parties, such as national governments, such that we or our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third-parties have ownership rights or other rights to our patents, including in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products, product candidates and technologies. For example, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act ("Bayh-Dole Act"), including a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights," which allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. If we choose to collaborate with academic institutions or other organizations subject to U.S. federal funds to accelerate our preclinical research or development, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with U.S. federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may use artificial intelligence ("AI") in our business, and challenges with properly managing its use, as well as uncertainty regarding the legal landscape surrounding the use of AI could adversely affect our business.

We currently do not use AI, machine learning, or automated decision-making technologies in connection with our product development, but we use commercially available AI technologies for office and administrative functions. There are significant risks involved in utilizing AI. Issues relating to the use of new and evolving technologies such as AI may cause us to experience brand or reputational harm, competitive harm, legal liability and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues. Known risks of AI currently include inaccuracy, bias, toxicity, intellectual property infringement or misappropriation, data privacy and cybersecurity issues and data provenance disputes. In addition, litigation or government regulation related to the use of AI may also adversely impact our and others' abilities to use AI, as well as increase the cost and complexity of doing so. Use of AI by people, including our vendors, employees, suppliers and contractors, with access to our proprietary and confidential information, including know-how, may continue to increase and may lead to the release of such information, which may impact our ability to realize the benefit of our intellectual property.

Risks Related to Indebtedness

Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations, and impair our ability to satisfy our obligations under the Convertible Notes.

As of December 31, 2025, we had $575 million principal amount of indebtedness as a result of the 2.25% Convertible Senior Notes due 2028 ("Convertible Notes") offering. We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our shareholders and our business, results of operations, and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing shareholders as a result of issuing ADSs upon conversion of the Convertible Notes and the ordinary shares represented by such ADSs; and

- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Convertible Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the Convertible Notes, and our cash needs may increase in the future. In addition, future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

We may be unable to raise the funds necessary to redeem the Convertible Notes for cash following a fundamental change, and our future indebtedness may limit our ability to redeem the Convertible Notes in connection with such fundamental change.

Holders of the Convertible Notes may, subject to a limited exception described in the indenture, require us to redeem their Convertible Notes following a fundamental change under the indenture at a cash fundamental change redemption price generally equal to the principal amount of the Convertible Notes to be redeemed in connection with such fundamental change, plus accrued and unpaid interest, if any. We may not have enough available cash or be able to obtain financing at the time we are required to redeem the Convertible Notes in connection with a fundamental change. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to redeem the Convertible Notes in connection with a fundamental change. Our failure to redeem Convertible Notes in connection with a fundamental change when required will constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our other consolidated indebtedness (if any), which may result in that other indebtedness becoming immediately payable in full. If the repayment of such other indebtedness were to be accelerated after any applicable notice or grace periods, then we may not have sufficient funds to repay that indebtedness and redeem the Convertible Notes in connection with such fundamental change.

Provisions in the indenture could delay or prevent an otherwise beneficial takeover of us.

Certain provisions in the Convertible Notes and the indenture could make a third party attempt to acquire us more difficult or expensive. For example, a takeover will under certain circumstances constitute a fundamental change, and the noteholders will then have the right to require us to redeem their Convertible Notes for cash.

In addition, if a takeover constitutes a make-whole fundamental change, then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the Convertible Notes and the indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that noteholders or holders of the ADSs or our ordinary shares may view as favorable.

The accounting method for the Convertible Notes could adversely affect our reported financial condition and results.

The Convertible Notes are treated as a compound financial instrument with a foreign currency financial liability component (“host”), and an embedded derivative (“derivative”) related to a written option to exchange a fixed number of our shares for a fixed amount of Convertible Notes that is denominated in a foreign currency. The derivative is not closely related to the host, because it is exposed to dissimilar risks, such as volatility from the Company’s own share price. Accordingly, the derivative is accounted for separately at fair value through profit or loss.

The initial fair value of the host was the residual amount after separating the embedded derivative at fair value, net of transaction costs attributable to the host component. Transaction costs were allocated to the host and the derivative in proportion to the allocation of proceeds. Transaction costs attributable to the derivative were recognized immediately in the profit or loss as a financial expense.

The difference between the principal amount of the Convertible Notes and the initial fair value of the host is amortized into interest expense over the expected lifetime of the Convertible Notes using the effective interest method. As a result of this amortization, the interest expense that we expect to recognize for the Convertible Notes for accounting purposes will be greater than the cash interest payments we will pay on the Convertible Notes, which will result in lower reported income or higher reported loss. The lower reported income or higher reported loss resulting from this accounting treatment could depress the trading price of our ADSs and the Convertible Notes.

The fair value of the derivative cannot be measured based on quoted prices in active markets, or other observable input, and accordingly, the derivative is measured by using the Black-Scholes option-pricing model, where the pricing is exposed from changes in the Company's share price. Since the fair value is exposed to development in the Company's share price, the profit or loss is exposed to volatility from such development, which could result in lower reported income or higher reported loss. The lower reported income or higher reported loss resulting from this accounting treatment could have a negative effect on the trading price of the ADSs.

In addition, the accounting method for reflecting the ordinary shares represented by ADSs underlying the Convertible Notes in our diluted earnings per share may adversely affect our reported earnings and financial condition. We expect that, under applicable accounting principles, the ordinary shares represented by ADSs underlying the Convertible Notes will be reflected in our diluted earnings per share assuming that all the Convertible Notes were converted into ADSs at the beginning of the reporting period (or, if later, the date the Convertible Notes are first issued), unless the result would be antidilutive. Accounting for the Convertible Notes in this manner may reduce our diluted earnings per share.

Risks Related to Our Ordinary Shares and ADSs

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

The trading price of the ADSs has been and could continue to 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:

- our ability to commercialize or obtain regulatory approval for our products or product candidates, or delays in commercializing or obtaining regulatory approval;
- results from, or any delays in, clinical trial programs relating to our products or product candidates;
- our ability to apply our TransCon technologies to therapeutic areas other than endocrinology, including the therapeutic areas of oncology and ophthalmology;
- announcements of regulatory approval or a complete response letter to our product candidates, or specific label indications or patient populations for use, or changes or delays in the regulatory review process;
- announcements relating to current or future collaborations or joint ventures;
- announcements of therapeutic innovations or new products by us or our competitors;
- announcements regarding the parent drugs that we use in developing our product candidates;
- adverse actions taken by regulatory authorities with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our products or product candidates;
- any adverse changes to our relationship with any manufacturers or suppliers;
- the success of our testing and clinical trials;

- the success of our efforts to acquire, license or discover additional products or 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 EU, United States or in other markets;
- changes in the structure of healthcare payment systems;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of the ADSs;
- sales or purchases of ordinary shares and/or ADSs by us, our senior management and board members, holders of the ADSs or our shareholders in the future;
- general economic and market conditions and overall fluctuations in the United States and international equity markets, including deteriorating market conditions due to investor concerns regarding inflation and hostilities between Russia and Ukraine and between Israel and Hamas;
- the effects on our business, operating results, prospects and financial condition of potential future pandemics such as COVID-19; and
- the loss of any of our key scientific or senior management personnel.

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

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

Danish law governs shareholder rights. Our depositary, The Bank of New York Mellon, is the holder of the ordinary shares underlying our ADSs through its custodian. The deposit agreement among us, the depositary, and all other persons directly and indirectly holding ADSs, sets out ADS holder rights as well as the rights and obligations of the depositary. In addition, our depositary charges and/or deducts certain fees to holders of the ADSs.

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

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

However, we may not request the depositary to distribute this information which could effectively limit the ability of ADS holders to direct voting of the ordinary shares underlying their ADSs.

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

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

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

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

We may from time to time issue additional shares or ADSs at a discount from the trading price of the ADSs.

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

Holders of ADSs and shareholders may experience future dilution as a result of exercise or conversion of warrants, RSUs, PSUs and convertible notes.

As of December 31, 2025, approximately 11.6 million ordinary shares that are subject to outstanding warrants, RSUs, PSUs, convertible notes or reserved for future issuance under our warrant incentive program are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and the terms of our convertible notes. Exercise or conversion of warrants and convertible notes may take place at a price below the market price of the ADSs at the time of exercise and may therefore result in dilution of the value of the ADSs. In addition, to the extent that RSUs or PSUs settle into ADSs, we would also issue to the holders of such RSUs or PSUs ADSs held by us.

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

If our existing shareholders or holders of ADSs sell, or indicate an intention to sell, substantial amounts of our ordinary shares or ADSs representing our ordinary shares in the public market, the trading price of the ADSs could decline. If our outstanding warrants are exercised or ADSs subject to restricted stock units and performance stock units vest and settle, additional ordinary shares or ADSs may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional ordinary shares or ADSs are sold, or if it is perceived that they will be sold, in the public market, the trading price of the ADSs could decline. Any sales of securities by these security holders could have a negative effect on the trading price of the ADSs.

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

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

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

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

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

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

The United States and Denmark currently do not have a treaty providing for the reciprocal recognition and enforcement of judgements, other than arbitration awards, in civil and commercial matters. Consequently, a final judgement for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Denmark. 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 for actual losses or damages. Enforcement and recognition of judgements of U.S. courts in Denmark are solely governed by the provisions of the Danish Administration of Justice Act.

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

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

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

Our status as a "foreign private issuer" allows us to adopt IFRS accounting principles, which are different from accounting principles under U.S. Generally Accepted Accounting Principles ("US GAAP").

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

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

As a foreign private issuer, in accordance with the listing requirements of the Nasdaq Global Select Market, we rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of the Nasdaq Global Select Market. For instance, the Listing Rules for The Nasdaq Stock Market ("Nasdaq Listing Rules"), for domestic U.S. issuers require listed companies to have, among other things, a majority of their board members be independent, and to have independent director oversight of executive compensation, nomination of board members and corporate governance matters. As a foreign private issuer, however, while we intend to comply with these requirements, we are permitted to follow home country practice in lieu of the above requirements. Danish law does not require that a majority of our board consist of independent directors or the implementation of a remuneration committee or nominating and corporate governance committee, and our board may thus in the future not include, or include fewer, independent directors than would be required if we were subject to the Nasdaq Listing Rules, or they may decide that it is in our interest not to have a remuneration committee or nominating and corporate governance committee, or have such committees governed by practices that would not comply with The Nasdaq Listing Rules.

Since a majority of our board of directors may not consist of independent directors, if we decide to rely on the foreign private issuer exemption to The Nasdaq Listing Rules, our board's approach may, therefore, be different from that of a board with a majority of independent directors, and as a result, the management oversight of our company could, in the future, be more limited than if we were subject to The Nasdaq Listing Rules. We intend to follow home country practice with regard to, among other things, quorum requirements generally applicable to general meetings of shareholders.

Furthermore, Danish law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in Denmark, thus our practice varies from the requirement of Nasdaq Listing Rule 5620(b). In addition, our shareholders have authorized our board of directors to issue securities including in connection with certain events such as the acquisition of shares or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us, rights issues at or below market price, certain private placements and issuance of convertible notes. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. Accordingly, our shareholders and holders of the ADSs 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, 2026, 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, 2027. To maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares or ADSs must be either directly or indirectly owned of record by non-residents of the United States or (b) (i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must not be administered principally inside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage.

These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors and members of our senior management.

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

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

Under Danish corporate law, except in certain limited circumstances (which require as a minimum that a proposal for inspection has been supported by a minimum of 25% of share capital), our shareholders may not ask for an inspection of our corporate records, while under Delaware corporate law any shareholder, irrespective of the size of such shareholder's shareholdings, may do so. Shareholders of a Danish limited liability company are also unable to initiate a derivative action, a remedy typically available to shareholders of U.S. companies, to enforce a right of our company, in case we fail to enforce such right ourselves, other than in certain cases of board member or 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 or 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 may be subject to non-refundable withholding tax, which may not be creditable or deductible under the tax laws of the country in which the recipient shareholder is resident for tax purposes. 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. Further, repurchases of ordinary shares or ADSs by Ascendis Pharma A/S may have adverse tax consequences to us or shareholders under applicable Danish law. Finally, Danish corporate law may not provide appraisal rights in the case of a business combination equivalent to those generally afforded a shareholder of a U.S. company under applicable U.S. laws. As a result of these differences between Danish corporate law and our articles of association, on the one hand, and U.S. federal and state laws, on the other hand, in certain instances, shareholders and ADS holders could receive less protection as an equity holder of our company than they would as a shareholder of a U.S. company.

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

Under the Danish Companies Act, our shareholders benefit from a pre-emptive subscription right on the issuance of ordinary shares for cash consideration only and not in the event of issuance of shares against non-cash contribution or debt conversion. Even the shareholders' pre-emptive subscription rights in the event of issuances of shares against cash payment may be disapplied by a resolution of the shareholders at a general meeting of our shareholders and/or the shares or ADSs may be issued on the basis of an authorization granted to the board of directors pursuant to which the board may disapply the shareholders' pre-emptive subscription rights. Such shares or ADSs may be issued above, or at market value. In addition, a shareholder may not be able to exercise the shareholder's pre-emptive right on a timely basis or at all, unless the shareholder complies with the Danish Companies Act and applicable laws in the jurisdiction in which the shareholder is resident. Furthermore, the use of pre-emptive subscription rights in relation to future capital increases in our company can be restricted for U.S. residents according to U.S. securities law. As a result, the shareholding or holding of ADSs of such shareholders or ADS holders may be materially diluted in the event shares or ADSs are issued in the future.

Shares or ADSs may be issued at a discount to market price in rights offerings provided that the resolution is approved by two-thirds of the votes cast and the share capital represented at the general meeting and in these cases a restriction on the ability to exercise pre-emptive rights may materially dilute the value of the ordinary shares or ADSs held by the shareholder or ADS holder in question. Rights issues may also be carried out by the board of directors according to valid authorizations in our articles of association. Issuance of shares at a discount to market price in a directed offering without pre-emptive rights for existing shareholders or holders of ADSs requires approval from the shareholders with 90% of the votes cast and the share capital represented at the general meeting.

However, ADS holders in the United States are not entitled to exercise or sell such pre-emptive subscription rights related to the ordinary shares, which they represent unless we register the pre-emptive subscription rights and the securities to which the pre-emptive subscription rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary will not make rights available to ADS holders unless the distribution to ADS holders or both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act.

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

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

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

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

Under the Internal Revenue Code of 1986, as amended ("Code"), and U.S. Treasury Regulations, the determination of passive foreign investment company ("PFIC") status is fact-specific, and generally cannot be made until after the close of the taxable year in question. Based on our market capitalization and the composition of our income, assets and operations, we do not believe we were a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2025. However, this is a factual determination, and the application of the PFIC rules is subject to uncertainty in several respects, and we cannot assure you we will not be a PFIC for any taxable year. A non-U.S. corporation will be considered a PFIC for any taxable year if, after the application of certain look-through rules, either (1) at least 75% of its gross income for such taxable year is passive income (as defined in the relevant provisions of the Code) or (2) at least 50% of the value of its assets (generally based on an average of the quarterly values of the assets) during such year is attributable to assets that produce or are held for the production of passive income. A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). If we are a PFIC for any taxable year during which a U.S. Holder (as defined in "Item 10 E. Additional Information – Taxation – Material U.S. Federal Income Tax Consequences to U.S. Holders") holds ordinary shares or ADSs, the U.S. Holder may be subject to adverse tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of an interest charge with respect to such gain and certain dividends and (iii) compliance with certain reporting requirements. Although we do not believe we were a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2025, the application of the PFIC rules is subject to uncertainty in several respects. Whether we will be a PFIC in any year depends on the composition of our income and assets, and the relative fair market value of our assets from time to time, which we expect may vary substantially over time. In addition, because the value of our assets, including unbooked goodwill, for purposes of the asset test will generally be determined by reference to the market price of the ADSs, our PFIC status will depend in large part on the market price of the ADSs, which may fluctuate significantly. For these reasons, we cannot assure you we will not be a PFIC for any taxable year.

Each U.S. Holder is strongly urged to consult its tax advisor regarding these issues. See "Item 10 E. Additional Information – Taxation – Material U.S. Federal Income Tax Consequences to U.S. Holders."

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

If a U.S. Holder (as defined in "Item 10 E. Additional Information – Taxation – Material U.S. Federal Income Tax Consequences to U.S. Holders") is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares or ADSs, such U.S. Holder will be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group. Because our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries will be treated as "controlled foreign corporations" (regardless of whether we are treated as a "controlled foreign corporation") for our taxable years beginning before January 1, 2026. However, due to the legislative change in the attribution rules enacted in the OBBBA, signed into law on July 4, 2025, and effective for taxable years beginning January 1, 2026, our non-U.S. subsidiaries no longer will be treated as "controlled foreign corporations" solely due to the fact that our group includes one or more U.S. subsidiaries. For the years preceding 2026, a "United States shareholder" of a "controlled foreign corporation" may be required to report annually and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by "controlled foreign corporations," regardless of whether we make any distributions. Failure to comply with these reporting obligations may subject a "United States shareholder" to significant monetary penalties and may prevent the statute of limitations from starting with respect to such shareholder's U.S. federal income tax return for the year for which reporting was due. Further, an individual that is a "United States shareholder" with respect to a "controlled foreign corporation" generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a "United States shareholder" that is a U.S. corporation. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries are treated as a "controlled foreign corporation" or whether such investor is treated as a "United States shareholder" with respect to any of such "controlled foreign corporations" for the years preceding 2026. Further, we cannot provide any assurances that we will furnish to any "United States shareholders" information that may be necessary to comply with the aforementioned reporting and tax payment obligations.

U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares or ADSs.

We could be adversely affected by changes in tax laws and regulations and the interpretation thereof.

Our tax liabilities could be adversely affected by several factors, including changing tax laws, regulations and treaties, or the interpretation thereof; tax policy initiatives and reforms implemented or under consideration; the practices of tax authorities in jurisdictions in which we operate; and the resolution of issues arising from tax audits or examinations and any related interest or penalties. For example, legislation has been enacted or is currently under consideration in a number of jurisdictions to adopt and implement Pillar Two of the base erosion and profit shifting ("BEPS") project initiated by the Organization for Economic Cooperation and Development ("OECD"), which is designed to introduce a global minimum tax rate of 15% for certain multinational groups. In December 2021 and March 2022, the OECD published model rules and related commentary to support member jurisdictions of the G20/OECD Inclusive Framework on BEPS (including Denmark) to implement the Pillar Two framework. Denmark has transposed the rule into its tax legislation effective January 1, 2024. We are not subject to Pillar II rules until the consolidated turnover of Ascendis Pharma exceeds €750 million and certain other conditions are met. The ultimate impact of any such changes on our tax obligations remains uncertain and will continue to be monitored by us.

We are unable to predict what tax reforms may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices in jurisdictions in which we operate, could increase the estimated tax liability that we have expensed to date and paid or accrued on its consolidated statements of operations and comprehensive loss, and otherwise affect the future results of operations, cash flows in a particular period and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to shareholders and increase the complexity, burden and cost of tax compliance.

Item 4 Information on the Company

A. History and Development of the Company

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

Our registered office and principal executive offices are located at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark and our telephone number is +45 70 22 22 44. Our agent for service of process in the United States is Ascendis Pharma, Inc., located at 1000 Page Mill Road. Palo Alto, CA 94304. Our corporate website address is www.ascendispharma.com. The information on, or that can be accessed through, our website is not part of and should not be incorporated by reference into this annual report or any other report we file or furnish to the U.S. Securities and Exchange Commission ("SEC"). We have included our website address as an inactive textual reference only. Our ADSs are traded on The Nasdaq Global Select Market under the symbol "ASND."

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

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

B. Overview

Overview

We are a global biopharmaceutical company focused on applying our innovative TransCon technology platform to make a meaningful difference for patients. Guided by our core values of Patients, Science, and Passion, and following our algorithm for product innovation, we develop TransCon-based therapies that demonstrate best-in-class potential to address unmet medical needs. Our portfolio of Endocrinology Rare Disease approved products and product candidates addresses hypoparathyroidism and growth disorders. To create additional value, we have established partnerships to develop and bring to market TransCon-based products in large therapeutic areas, including Metabolic and Cardiovascular diseases and Ophthalmology.

Our Vision

As announced in January 2024, Vision 2030 is our vision to achieve blockbuster status for multiple products and expand our engine for future innovation,which include:

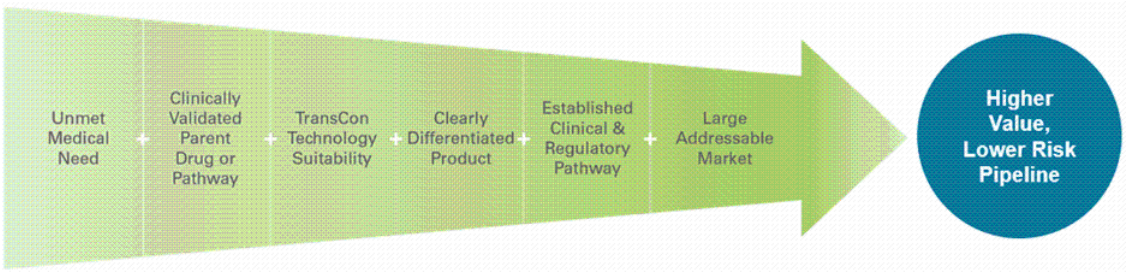
- Be the Leading Endocrinology Rare Disease Company
  - Achieve >€5B for TransCon PTH, TransCon hGH, and TransCon CNP through worldwide commercialization
  - Be the leader in growth disorders and hypoparathyroidism, pursuing clinical conditions, innovative life cycle management, and complementary patient offerings
  - Expand pipeline with Endocrinology Rare Disease blockbuster product opportunities
- Create Value in Additional Therapeutic Areas through Innovative Business Models
  - Obtain accelerated approval in oncology with registrational trials ongoing
  - Pursue TransCon product opportunities in >€5B indications

- o Maximize value creation of these product opportunities through collaboration with therapeutic area market leaders
- Differentiate with Ascendis Fundamentals
  - o Outperform industry drug development benchmarks with Ascendis' product innovation algorithm
  - o Remain independent as a profitable biopharma through lean and flexible ways of working
  - o Let our values Patients, Science, Passion drive our decisions to success

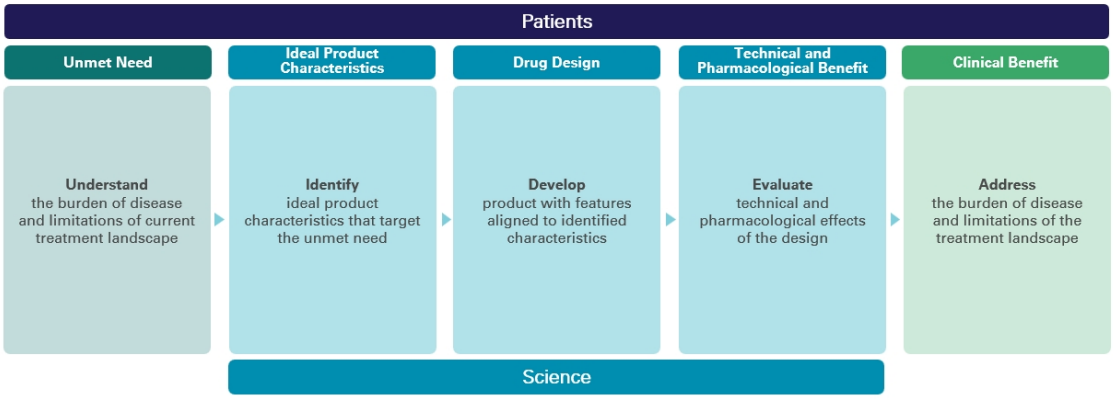
Our products and product candidates leverage clinically validated parent drugs or pathways, with the goal of optimizing safety, efficacy, tolerability, and convenience.

We apply our TransCon technologies using our algorithm for product innovation with the goal of creating product candidates with the potential to be best-in-class. Using this approach, we plan to expand our pipeline with Endocrinology Rare Disease product opportunities in large addressable markets. In addition, our vision is to pursue TransCon product opportunities in >€5B indications in other therapeutic areas and maximize value creation of these product opportunities through collaboration with therapeutic area market leaders. We believe our approach to product innovation may reduce the risks associated with traditional drug development.

Ascendis Algorithm for Product Innovation



Ascendis Approach to Patient Centric Drug Design



When we apply our TransCon technologies to clinically validated parent drugs or pathways, we may benefit from established clinical safety and efficacy data, which we believe increases the probability of success compared to traditional drug development. As illustrated above, our algorithm for product innovation focuses on identifying indications that have an unmet medical need, have a clinically validated parent drug or pathway, are suitable to our TransCon technologies, have potential for creating a clearly differentiated product, have a potential established development pathway, and have the potential to address a large market. When the indication is identified we make use of patient centric drug design to optimally apply our TransCon technologies to address the unmet medical need.

Program Summaries

We currently have two marketed products and a diversified portfolio consisting of four product candidates in clinical development in the areas of Endocrinology Rare Disease and Oncology. One of the four product candidates, TransCon CNP (navepegritide), is currently under review in the United States and European Union for the treatment of children with achondroplasia. Additionally, we are working to apply our TransCon technology platform in additional therapeutic areas such as metabolic diseases, where we believe we have designed a potentially best-in-class, once-monthly glucagon-like peptide 1 ("GLP-1") product.

- YORVIPATH® (palopegteriparatide), was developed as TransCon PTH and was approved by the U.S. Food & Drug Administration ("FDA"), and authorized by the European Commission ("EC") and other regulatory agencies for the treatment of adults with hypoparathyroidism. In the European Union ("EU"), YORVIPATH is commercially available for prescription in Germany, Austria, Spain and Luxembourg and is also available in other countries through named patient programs. In the United States, YORVIPATH has been commercially available for prescription since December 2024. In Japan, YORVIPATH has been commercially available for prescription since November 2025, through our partner Teijin Limited ("Teijin"). YORVIPATH has also been authorized by other regulatory authorities globally. Through December 31, 2025, more than 5,300 unique patients have been prescribed YORVIPATH by nearly 2,400 prescribing healthcare providers in the U.S.
- SKYTROFA® (lonapegsomatropin-tcgd) was developed as TransCon hGH and approved by the FDA for the treatment of pediatric patients one year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone, also known as growth hormone deficiency ("GHD") and for the replacement of endogenous growth hormone in adults with GHD. SKYTROFA has been commercially available for prescription in the United States since October 2021. In addition, the EC has authorized SKYTROFA (lonapegsomatropin) in the EU for the treatment of children and adolescents (3 – 18 years) with growth failure due to GHD. In the EU, SKYTROFA has been commercially available for prescription in Germany since September 2023. SKYTROFA has also been authorized by other regulatory authorities globally including in China through our strategic collaboration partner, VISEN Pharmaceuticals ("VISEN") in January 2026.
- *Endocrinology Rare Disease Pipeline* – Two product candidates in our Endocrinology Rare Disease portfolio are currently in development for additional indications and geographies. These product candidates are TransCon hGH (lonapegsomatropin) for children with Turner syndrome and TransCon CNP (navepegritide) for infants, children, and adolescents with achondroplasia. We are also investigating the combination of TransCon CNP and TransCon hGH in children with achondroplasia and other indications. In addition, we are investigating TransCon hGH in other established daily growth hormone indications and TransCon CNP, alone and in combination with TransCon hGH, for the treatment of children with hypochondroplasia, a related FGFR3-driven skeletal dysplasia. Through our strategic collaboration, Teijin is developing and, if approved, plans to commercialize TransCon hGH, and TransCon CNP for endocrinology rare diseases in Japan. In addition, VISEN is developing and, if approved, plans to commercialize TransCon PTH, and TransCon CNP for endocrinology rare diseases in the People's Republic of China, Hong Kong, Macau, and Taiwan ("Greater China").
- *Oncology Pipeline* – In Oncology, we are leveraging our TransCon technologies with the goal of enhancing the anti-tumor effects of clinically-validated parent drugs and pathways and to provide sustained modulation of tumor microenvironments and activate cytotoxic immune cells. We initiated clinical development of two programs: TransCon TLR7/8 Agonist, an investigational, long-acting prodrug of resiquimod, a small molecule agonist of Toll-like receptors ("TLR") 7 and 8, for intratumoral delivery, and TransCon IL-2 b/g (onvapegleukin alfa) for systemic delivery, which is designed for prolonged exposure to an IL-2 variant that selectively activates IL-2 b/g with minimal binding to IL-2Rα. During the fourth quarter of 2024, we closed enrollment in our BelieveIT-201 clinical trial and to dose expansion cohorts involving TransCon TLR7/8 Agonist in the transcendIT-101 and IL-Believe trials to prioritize our efforts on TransCon IL-2 b/g.

TransCon Product Candidates Pipeline

Other than the rights we have granted to Eyconis, Inc. ("Eyconis"), Novo Nordisk A/S ("Novo Nordisk"), Teijin, and VISEN as noted in this report, we hold worldwide rights to our TransCon technologies and, other than our royalty financing arrangements with Royalty Pharma as noted in this report, we owe no third-party royalty or milestone payment obligations with respect to our TransCon technologies, TransCon hGH, TransCon PTH, TransCon CNP, or any of our other product candidates.

Endocrinology Rare Diseases		Indication	Status	Region
Lead indication	**TransCon CNP**	Achondroplasia (children aged 2–11)	NDA and MAA Accepted [1]	Multinational
	TransCon CNP	Achondroplasia (children)	Long-Term Extension Trial [2]	Multinational
Label Expansion	**TransCon hGH**	Turner syndrome (children aged 1–10)	Phase 2 [3]	U.S.
	TransCon hGH	Multi-Indication (children aged 2-17)	Phase 3 [4]	Multinational
	TransCon PTH	Hypoparathyroidism (adults)	Phase 3 [5]	U.S
	TransCon PTH	Hypoparathyroidism (adolescents)	Phase 3 [6]	Multinational
	TransCon CNP	Achondroplasia (infants)	Pivotal Phase 2 [7]	Multinational
	TransCon CNP	Achondroplasia (adolescents)	Pivotal Phase 2b [8]	Multinational
	TransCon CNP	Hypochondroplasia (children aged 2-17)	Phase 3 [9]	Multinational
	TransCon CNP + TransCon hGH	Achondroplasia (children aged 2–11)	Phase 2 [10]	Multinational
	TransCon CNP + TransCon hGH	Achondroplasia (children aged 2–17)	Phase 3 [11]	Multinational
	TransCon CNP + TransCon hGH	Hypochondroplasia (children aged 2-17)	Phase 3 [12]	Multinational
	TransCon hGH	Pediatric GHD	Phase 3 [13]	Japan
	TransCon PTH	Hypoparathyroidism (adults)	Completed Phase 3 [14]	China
	TransCon CNP	Achondroplasia	Completed Phase 2 [15]	China
	TransCon CNP	Achondroplasia	Phase 3 [16]	Japan
Oncology		**Indication**	**Status**	**Region**
Lead Indication	**TransCon IL-2 β/γ**	Various tumor types	Phase 2 [17]	Multinational

Note: The above chart lists our current clinical interventional trials related to the disclosed indication. Other ongoing clinical or observational studies not expected to directly support regulatory submissions are not disclosed.

1. *ApproaCH Trial (NCT05598320). Priority Review granted by U.S. FDA, PDUFA goal date February 28, 2026.*
2. *AttaCH Trial (NCT05929807). Includes patients from ACcomplisH and ApproaCH.*
3. *New InsiGHTS Trial (NCT05690386).*
4. *HighLiGHts Trial (NCT07221851).*
5. *PaTHway60 Trial (NCT07081997).*
6. *PaTHway Adolescent Trial (NCT05203198).*
7. *reACHin Trial (NCT06079398).*
8. *teACH Trial (NCT06732895).*
9. *Hypochondroplasia Monotherapy Trial (NCT pending).*
10. *COACH Trial (NCT06433557).*
11. *Trial Protocol filed (NCT pending).*
12. *Hypochondroplasia Combination Trial (NCT pending).*
13. *Japanese riGHt Trial.*
14. *PaTHway China Trial (NCT05387070).*

15. *ACcomplisH China Trial (NCT05246033).*
16. *Japanese ApproaCH Trial.*
17. *IL-Believe Trial (NCT05081609).*

We maintain an intellectual property portfolio comprising over 465 granted patents and over 625 patent applications as of December 31, 2025, which includes patents and patent applications applicable to our products and product candidates with claims directed to composition of matter, process, formulation and/or methods-of-use for our products and product candidates, including a product-specific device and core TransCon technologies. While our TransCon prodrugs may incorporate already approved parent drugs or product candidates, TransCon hGH, TransCon PTH, TransCon CNP, and each of our other product candidates are new molecular entities and therefore eligible to be granted new intellectual property rights, including new composition of matter patents.

Global Commercialization Strategy

We are establishing a global presence to commercialize TransCon products, where approved, to address patients' unmet medical needs.

In the U.S., we have established an integrated organization to commercialize our approved Endocrinology Rare Disease products, YORVIPATH and SKYTROFA. Our U.S. organization includes various departments, including sales, market access, patient support, and medical affairs teams. The sales team engages with healthcare providers to present products, usage, and safety guidelines in accordance with the label. Our market access team engages with health authorities, insurance companies, and payers to support patients in need of gaining access to our products. Our patient support team facilitates reimbursement support and out-of-pocket assistance and provides educational resources and product training. Our medical affairs team engages in scientific exchange with the physician and medical community. We have also established a network of specialty pharmacies to support product distribution.

In Europe, we have established our presence by building integrated organizations to commercialize our approved Endocrinology Rare Disease products in select countries, which we call "Europe Direct." Our Europe Direct country clusters include DACH (Germany, Austria, and Switzerland), France & BeNeLux (Belgium, the Netherlands, and Luxembourg), Iberia (Portugal and Spain), Italy, Nordics (Denmark, Norway, Sweden, Iceland, and Finland), and the United Kingdom & Ireland.

Beyond the U.S. and Europe Direct, we are expanding global reach for our Endocrinology Rare Disease products through exclusive sales and distribution agreements with geographic market leaders, which we call "International Markets." As of December 31, 2025, we have agreements covering over 75 countries.

Finally, we are making our Endocrinology Rare Disease products commercially available in China and Japan under exclusive license agreements with partners with local development and commercialization expertise and infrastructure, which we call strategic collaborations. In Japan, Teijin has exclusive license rights to develop and commercialize TransCon hGH, TransCon PTH, and TransCon CNP. In Greater China, VISEN has exclusive license rights to develop and commercialize TransCon hGH, TransCon PTH, and TransCon CNP.

Demand for our products has not been subject to material seasonal changes.

On April 2, 2025, an executive order was issued in the United States implementing "Reciprocal Tariffs" on most U.S. trading partners, with a 10% baseline tariff on imports from most trading partners and an additional individualized reciprocal tariff on countries with larger trade deficits. After a series of pauses in implementation, on August 7, 2025, these tariffs went into effect. Some goods will not initially be subject to the Reciprocal Tariffs, including pharmaceuticals. While there can be no assurance that pharmaceuticals will remain free from Reciprocal Tariffs or other trade barriers in the future, we currently believe the impact of the Reciprocal Tariffs on our operations will be immaterial. As the Reciprocal Tariffs remain subject to ongoing scrutiny, including ongoing review by the Supreme Court of the United States, we continue to monitor and assess the possible impacts of existing and potential tariffs on our operations.

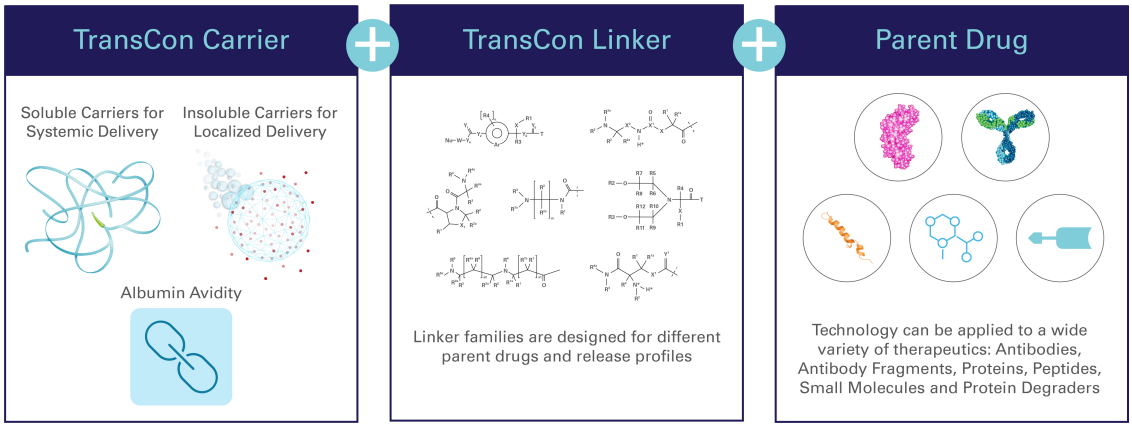
TransCon Technologies

Overview

Our TransCon technologies are designed to combine the benefits of conventional prodrug and sustained release technologies to solve the fundamental limitations seen in other approaches to extending duration of a drug's action in the body, with the goal of developing highly differentiated product candidates based on efficacy, safety, tolerability, and convenience. In addition to retaining the original mode of action of the parent drug and potentially supporting dosing frequency from daily up to six months or more, we believe that predictable release over time can improve treatment safety and efficacy, increase the likelihood of clinical development success, and provide intellectual property benefits.

TransCon prodrugs can have up to three components: a parent drug, an inert TransCon carrier that protects it, and a TransCon linker that temporarily binds the two. When bound in prodrug form, the carrier inactivates the parent drug and shields it from receptor uptake, renal clearance, and enzymatic degradation. When injected into the body, physiologic pH and temperature conditions initiate sustained release of the active, unmodified parent drug at a predictable rate.

Depending upon the type of TransCon carrier we employ, we can design our TransCon prodrugs for sustained localized or systemic delivery.

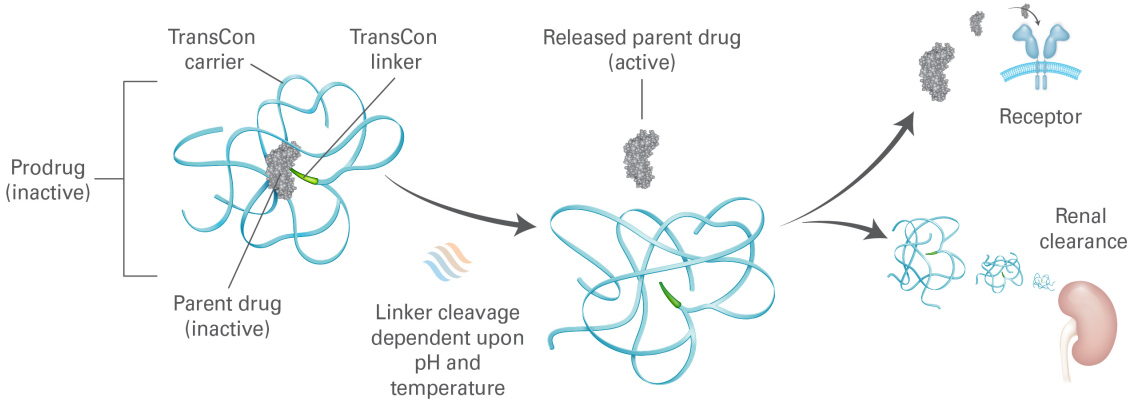


TransCon Technology Components

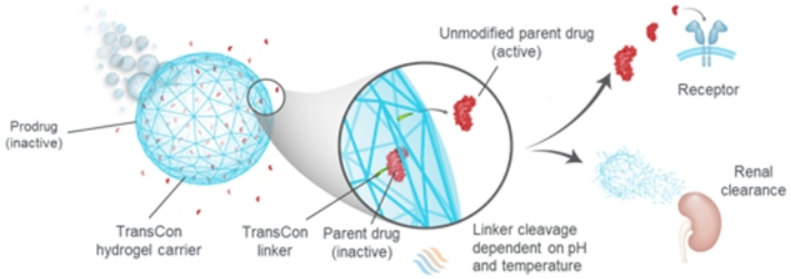
TransCon Carriers

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

- *Systemic* – Our TransCon systemic carriers are used to provide systemic drug exposure and are based on soluble compounds such as methoxypolyethylene glycol ("mPEG") or other natural or synthetic polymers, as well as our albumin avidity approach, where 2 or more albumin binding moieties are incorporated into the drug molecule to facilitate sustained exposure. Prodrugs created using our systemic carriers are readily absorbed into the bloodstream after administration, thus minimizing exposure of the subcutaneous tissue to active drug, which we believe may improve injection site tolerability. TransCon hGH, TransCon PTH, and TransCon CNP utilize mPEG as a carrier molecule. mPEG is widely used to improve the pharmacokinetic or pharmacodynamic properties of marketed therapeutics. Below is an illustration of our systemic carrier:



- *Localized* – Our TransCon localized carriers include TransCon hydrogels based on PEG, hyaluronic acid, or other biopolymers. TransCon hydrogel is designed to self-eliminate to soluble, biocompatible molecules after the drug payload has been released. When applied for localized delivery, the TransCon hydrogel enables the release of a parent drug at high local concentrations within the target area while minimizing systemic exposure. We believe this may widen the therapeutic window for parent drugs that suffer from significant systemic side effects and toxicities, facilitating the development of highly efficacious product candidates with improved safety and tolerability profiles. Below is an illustration of our hydrogel carrier:



TransCon Linkers

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

Parent Drugs

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

This approach has enabled us to develop two approved products and generate a pipeline of product candidates designed to address significant unmet medical needs. Because our TransCon technologies leverage clinically validated parent drugs or pathways, we believe we may benefit from a higher development and regulatory success rate compared to development of drug compounds without established biology.

TransCon Products and Product Candidates - Endocrinology Rare Disease

Hypoparathyroidism

Overview of Hypoparathyroidism

Hypoparathyroidism is a rare endocrine disease caused by insufficient levels of parathyroid hormone ("PTH"). As reported in a 2016 paper by Clarke BL, et al. (J Clin Endocrinol Metab. 2016 Jun;101(6):2284-99), most patients with hypoparathyroidism (70-80% of cases) develop the disease following damage to or accidental removal of the parathyroid glands during thyroid surgery. Other etiologies include autoimmune disorders, genetic disorders such as autosomal dominant hypocalcemia type 1, and idiopathic causes. Conventional therapy with oral calcium and active vitamin D (also called calcitriol) does not effectively address the short-term symptoms, long-term complications, or quality-of-life impacts of hypoparathyroidism.

Individuals with hypoparathyroidism may experience a range of severe and potentially life-threatening short-term and long-term complications. Short-term symptoms of hypoparathyroidism include weakness; severe muscle cramps (tetany); abnormal sensations such as tingling, burning, and numbness (paresthesia); memory loss; impaired judgment; and headache. A survey published by Hadker et al. (Endocrine Pr. 20(7), 671–679), in 2014 of 374 individuals with hypoparathyroidism showed that 72% experienced more than ten symptoms in the preceding twelve months, with symptoms experienced for a mean of 13 ± 9 hours a day. Prolonged use of conventional therapy may increase the risk of major complications, such as calcium deposits in the brain, blood vessels, eyes, and soft tissues. According to a systematic review by Gosmanova et al. published in 2021, chronic hypoparathyroidism treated with conventional therapy is associated with higher rates of renal complications compared to the general population, including nephrolithiasis (up to 36%), nephrocalcinosis (up to 38%), and chronic kidney disease (up to 41%). Studies have found that the burden of hypoparathyroidism negatively impacts health-related quality of life ("QoL"), physical functioning, and psychological well-being. Compared with an age-matched general population sample, individuals with hypoparathyroidism have reported markedly lower health-related QoL, irrespective of serum calcium level, as measured by the physical ($P<0.001$) and mental ($P<0.001$) component scores of the 36-Item Short Form Health Survey (SF-36) as well as the EuroQol-5 Dimensions Visual Analogue Scale. As reported in a 2021 paper by Brod et al. (Qual of Life Res. 2021 Jan; 30(1):277-291), in interviews conducted on 42 individuals with hypoparathyroidism, 98% reported reduced functioning and well-being, including anxiety (81%), feeling sad or depressed (62%), and feeling irritable or short-tempered (43%) despite management with conventional therapy.

Hypoparathyroidism also imposes a substantial burden on the healthcare system despite the use of conventional therapy. For example, individuals with hypoparathyroidism may require hospitalizations or emergency department visits due to acute severe hypocalcemia (calcium crashes) and those with post-surgical hypoparathyroidism have an increased risk of hospitalization due to infection than age- and sex-matched controls from the general population. Individuals with hypoparathyroidism also have an increased risk of hospitalization due to renal complications, such as chronic kidney disease and renal failure, compared to age- and sex-matched controls. According to a retrospective review (Chen K, et al. *J Med Econ*. Nov 2019;22(11):1141-1152), published in 2019 of clinical burden and healthcare resource utilization showed that 90.7% of individuals had ≥1 hypoparathyroidism-related healthcare utilization event during a 12-month period, including 87.8% with ≥1 outpatient visit, 41% with ≥1 emergency department visit, and 19.5% with ≥1 hospitalization. The management of hypoparathyroidism is also associated with substantial economic burdens and consequences of hypoparathyroidism may negatively impact employment status and work productivity.

The 2022 Guidelines from the Second International Workshop addressing the prevention, diagnosis, and management of hypoparathyroidism was published in September 2022 in the Journal of Bone and Mineral Research and authored by leading clinicians from North America, Europe, and Asia. The authors suggest consideration of PTH replacement therapy in patients whose hypoparathyroidism is inadequately controlled with conventional therapy. Inadequate control is considered to be any one of the following: symptomatic hypocalcemia, hyperphosphatemia, renal insufficiency, hypercalciuria, or poor quality of life. In addition, the guideline indicates that individuals with poor compliance, malabsorption, or intolerant of large doses of calcium and active vitamin D may also benefit from PTH replacement therapy. Based on this current guideline, we believe PTH replacement therapy could be applicable to most patients with hypoparathyroidism.

In 2015, Takeda's NATPARA® (parathyroid hormone) was approved in the U.S. for once-daily subcutaneous injection as an adjunct to vitamin D and calcium in patients with hypoparathyroidism. NATPARA was voluntarily recalled in September 2019 in the U.S. and is now only available to a limited number of patients through a Special Use Program offered by its manufacturer, Takeda. In October 2022, Takeda announced that it would discontinue manufacturing NATPARA/NATPAR globally by the end of 2024. In December 2025, Takeda announced that the NATPARA Special Use Program would permanently close on December 31, 2025, after which no patients would have access to NATPARA in the United States.

Other companies and groups are developing therapies for hypoparathyroidism at the clinical stage, including Calcilytix (a BridgeBio company), Entera Bio/Opko Health, Extend Biosciences, AstraZeneca, MBX Biosciences, and Septerna.

Forteo® (teriparatide, PTH [1-34]), approved since 2002 for the treatment of osteoporosis, has sometimes been used for treatment of hypoparathyroidism using multiple daily injections, despite not being approved for this indication. Clinical research conducted by the U.S. National Institutes of Health in subjects receiving continuous exposure to PTH (1-34), administered by an infusion pump, demonstrated simultaneous normalization of serum calcium and urinary calcium, as well as normalization of bone turnover.

We estimate hypoparathyroidism affects more than 250,000 patients in the U.S. and Europe. In the U.S., we estimate hypoparathyroidism affects approximately 70,000 to 90,000 patients, including 4,000 to 5,000 patients who we estimate have previously been treated with PTH therapy. In Germany, we estimate hypoparathyroidism affects approximately 70,000 patients. Outside of Germany, we estimate hypoparathyroidism affects more than 100,000 patients in the rest of Europe.

TransCon PTH

TransCon PTH (palopegteriparatide) is a prodrug of PTH (1-34) that is administered once-daily to achieve and maintain a steady concentration of PTH in the bloodstream within the physiological range. TransCon PTH is designed to provide PTH in the physiological range for 24 hours per day, thereby more fully addressing aspects of the disease, including maintaining normal serum calcium and phosphate levels and normalizing urinary calcium.

TransCon PTH for the Treatment of Hypoparathyroidism

In November 2025, Teijin announced that YORVIPATH is commercially available for prescription.

In August 2024, the FDA approved YORVIPATH (palopegteriparatide; developed as TransCon PTH) for the treatment of hypoparathyroidism in adults. In September 2024, the FDA granted Orphan Drug exclusivity to YORVIPATH, providing seven years of market exclusivity for YORVIPATH in the United States for the treatment of hypoparathyroidism in adults. YORVIPATH has been commercially available for prescription since late December 2024 in the United States.

In April 2024, TransCon PTH received regulatory approval in Great Britain as a PTH replacement therapy indicated for the treatment of adults with chronic hypoparathyroidism. In addition, in April 2024, we announced that the United Kingdom's Medicines & Healthcare products Regulatory Agency granted YORVIPATH Orphan Drug status.

In January 2024, we announced commercial availability of YORVIPATH in Germany and Austria, and we began shipping to customers in February 2024.

In November 2023, TransCon PTH received regulatory approval in the EU and European Economic Area and is marketed as YORVIPATH (palopegteriparatide), a parathyroid hormone replacement therapy indicated for the treatment of adults with chronic hypoparathyroidism. In addition, YORVIPATH was granted Orphan status in the EU in November 2023 and provides ten years of market exclusivity.

In July 2021, the Ministry of Health, Labour and Welfare in Japan granted Orphan Drug Designation ("ODD") to TransCon PTH for the treatment of hypoparathyroidism.

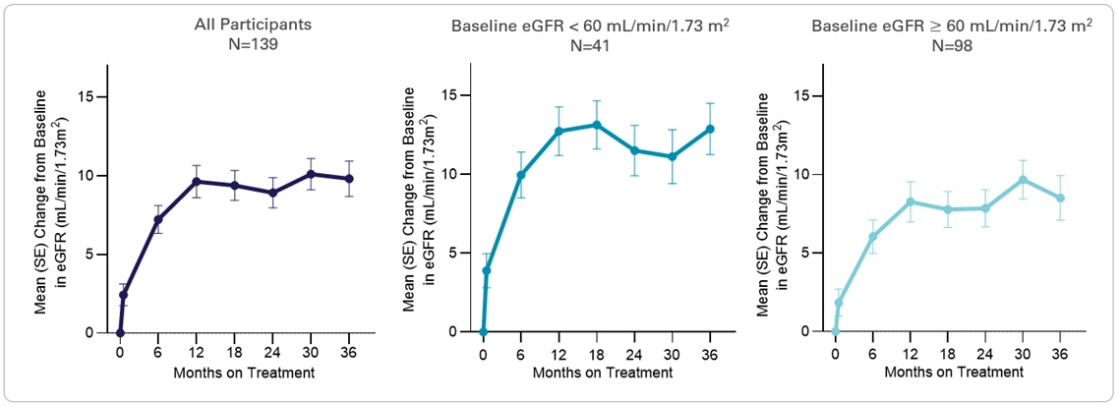
Clinical Development of TransCon PTH for Treatment of Hypoparathyroidism in Adults

TransCon PTH was evaluated for the treatment of hypoparathyroidism in adults in the Phase 3 PaTHway Trial, Phase 3 PaTHway Japan Trial (open label extension ongoing), and the Phase 2 PaTH Forward Trial.

The PaTHway Trial completed with 73 of 82 patients originally enrolled and dosed completing the 3.5-year trial. Nine patients withdrew from the trial for reasons unrelated to safety.

The PaTH Forward Trial recently completed with 56 patients out of 59 patients originally enrolled and dosed completing the five-year trial. Three patients withdrew from the trial for reasons unrelated to safety or efficacy of the study drug.

In November 2025, we presented a new pooled analysis showing sustained and clinically meaningful improvements in renal function in adults with hypoparathyroidism treated with TransCon PTH (palopegteriparatide) through Year 3 of our Phase 2 PaTH Forward and Phase 3 PaTHway trials.



The trials included a combined 141 adults with hypoparathyroidism, 139 of whom (mean age 49 years) are represented in the pooled analysis. The PaTH Forward and PaTHway trials comprised randomized, double-blind, placebo-controlled periods through Weeks 4 and 26 and open-label extension periods through Weeks 266 and 182, respectively. An eGFR ≥30 mL/min/1.73 m^2 was required for trial eligibility. The three-year data were analyzed post-hoc and included evaluation of the long-term impact of TransCon PTH on renal function as assessed by eGFR. Mean (SD) baseline eGFR in the trials was 69 (17) mL/min/1.73 m^2. The pooled analysis included 41 patients with baseline eGFR <60 mL/min/1.73 m^2 and 98 patients with baseline ≥60 mL/min/1.73 m^2. Safety assessments included 24-hour urine calcium excretion and treatment-emergent adverse events (TEAEs).

At Year 3, ≥91% of patients receiving palopegteriparatide in both trials were independent from conventional therapy (defined as taking no active vitamin D and ≤600 mg/day of calcium) and ≥84% patients had normocalcemia (8.3-10.6 mg/dL). Sustained and clinically meaningful improvements in eGFR (≥5 mL/ min / 1.73 m^2) were observed in 70.3%, with numerically greater improvements observed in those with lower baseline eGFR. The greatest increases in eGFR were observed in the first 6 months of treatment with TransCon PTH, with a continued upward trend thereafter. Mean (SD) eGFR increased from baseline to Year 3 by 9.8 (10.9) mL/min/1.73 m^2 in PaTH Forward and by 8.8 (11.9) mL/min/1.73 m^2 in PaTHway.

In July 2025, we announced new data from Week 156 of our Phase 3 PaTHway Trial, confirming that long-term treatment with TransCon PTH (palopegteriparatide) continued to provide a durable response in adults with hypoparathyroidism regardless of its cause (post-surgical, autoimmune, genetic, or idiopathic), including improvements in biochemistries, kidney function, and quality of life. At Week 156, 64 patients (88%) had normal albumin-adjusted serum calcium levels and 70 patients (96%) were independent from conventional therapy (defined as taking ≤ 600 mg/day of calcium and not taking active vitamin D). Reflecting clinically meaningful improvements in kidney function, improvements in eGFR from baseline were sustained through Week 156: mean eGFR increased by 8.76 mL/min/1.73 m^2 across all participants and by 13.98 mL/min/1.73 m^2 in participants with baseline eGFR < 60. Patients in the trial reported continued improvements from baseline in their hypoparathyroidism-related symptoms and health-related QOL and showed continued normalization of 24-hour urine calcium excretion through Week 156. In the trial, TransCon PTH treatment was generally well-tolerated, with no new safety signals identified. TEAEs were mostly mild or moderate and no serious TEAEs or discontinuations were related to study drug.

In May 2025, we announced four-year (Week 214) results from our Phase 2 PaTH Forward Trial showing that long-term treatment with TransCon PTH (palopegteriparatide) continued to provide a durable response in adults with hypoparathyroidism. At Week 214, nearly all patients (98%) continued to have normal albumin-adjusted serum calcium levels and 93% remained independent from conventional therapy (defined as taking ≤ 600 mg/day of calcium and not taking active vitamin D). Bone turnover markers CTx and P1NP increased from the low end of normal at baseline, peaked by Week 26, then declined and remained stable above baseline levels through Week 214. The data also showed continued improvement in skeletal dynamics, with bone mineral density remaining within age- and sex-matched norms. In addition, at Week 214, most participants (67.8%) had a clinically meaningful (≥ 5 mL/min/1.73 m^2) increase in eGFR from baseline, with changes in eGFR evident at Week 4. In the trial, TransCon PTH treatment was generally well-tolerated, with no new safety signals identified. TEAEs were mostly mild or moderate and no serious TEAEs or discontinuations were related to study drug.

In September 2024, we announced results from the Phase 2 PaTH Forward Trial of adults with hypoparathyroidism showing that long-term treatment with TransCon PTH (palopegteriparatide; marketed as YORVIPATH) through Week 162 drove bone remodeling into the normal range. Deficiency of PTH is associated with low rates of bone remodeling, accumulation of overly mature bone, and higher-than-average bone mineral density that may correspond with poorer overall bone quality compared to that seen in the general population. In contrast, these results suggest that long-term palopegteriparatide treatment promotes attainment of skeletal health parameters in line with those expected with states of parathyroid sufficiency.

In May 2024, we announced two-year (Week 104) results from a post-hoc analysis of the Phase 3 PaTHway Trial demonstrating sustained improvements (nominal p-value <0.05) in renal function in adults with chronic hypoparathyroidism treated with TransCon PTH. The post-hoc analysis examined the impact of treatment with TransCon PTH on renal function using estimated glomerular filtration rate ("eGFR") through Week 104 (n=76) of PaTHway, a Phase 3, double-blind, placebo-controlled trial of 82 dosed adults with chronic hypoparathyroidism randomized 3:1 (TransCon PTH: placebo; both arms initially co-administered with conventional therapy of active vitamin D and calcium), with a 26-week blinded period followed by an ongoing 156-week open-label extension period. Across both treatment arms, TransCon PTH treatment resulted in a mean eGFR increase of 8.9 mL/min/1.73m^2 ($p<0.0001$) from baseline at Week 52, sustained at Week 104 with a mean change from baseline of 9.0 mL/min/1.73m^2 ($p<0.0001$). Treatment was generally well-tolerated, with no new safety signals.

On January 8, 2023, we announced top-line data from PaTHway Japan, a single-arm Phase 3 trial to evaluate the safety, tolerability, and efficacy of TransCon PTH in adults with hypoparathyroidism. The study achieved its primary objective, with top-line results consistent with our trials in North America and the EU. Twelve out of thirteen patients met the primary multi-component endpoint, which was defined as serum calcium levels in the normal range (8.3–10.6 mg/dL) and independence from conventional therapy (no active vitamin D and ≤600 mg/day of calcium). In this trial, TransCon PTH was generally well-tolerated, with no discontinuations related to study drug. The open-label extension ("OLE") of this trial has been extended, and all patients have transitioned into the Investigational Medical Product supply period designed to ensure continuous treatment through the launch of YORVIPATH in Japan. In November 2025, Teijin announced that YORVIPATH is commercially available for prescription.

In March 2022, we announced that top-line data from the randomized, double-blind, placebo-controlled portion of the Phase 3 PaTHway Trial of TransCon PTH in adults with hypoparathyroidism demonstrated statistically significant higher proportion of participants treated with TransCon PTH achieved the primary multi-component endpoint compared to placebo. The primary endpoint, defined as serum calcium levels in the normal range (8.3–10.6 mg/dL) and independence from conventional therapy (no active vitamin D and ≤600 mg/day of calcium) with no increase in prescribed study drug within the 4 weeks prior to the Week 26 visit, was achieved by 78.7% of TransCon PTH-treated patients (48 of 61), compared to 4.8% for patients (1 of 21) in control group (p-value <0.0001). In addition, all key pre-specified secondary endpoints were met with statistical significance. TransCon PTH was generally well tolerated, with no discontinuations related to study drug. Three patients discontinued during the treatment period, two from the placebo arm and one from the TransCon PTH arm. TransCon PTH-treated patients showed a mean decrease in 24-hour urine calcium excretion into the normal range.

Growth Disorders

Market Opportunity for Recombinant Human Growth Hormone

GHD is a serious rare disease that affects both children and adults. Children with GHD are characterized by short stature, metabolic and cardiovascular abnormalities, cognitive deficiencies, and poor quality of life. GHD in adults is associated with increased adiposity, or fat mass, as well as psychiatric-cognitive, cardiovascular, muscular, metabolic and skeletal abnormalities. In childhood and adolescence, growth hormone plays an essential role in normal longitudinal growth, muscle and bone strength, and distribution of body fat. In adults, growth hormone contributes to body composition, cardiovascular function, and bone health. The current standard of care for GHD has been daily subcutaneous injections of somatropin, a recombinant human growth hormone ("hGH"). These daily hGH therapies have been shown to be safe and well-tolerated.

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

Despite the demonstrated benefits of daily hGH therapy, many GHD patients are not adequately treated, and adherence continues to be a challenge, as reported in a 2021 paper published by Kaplowitz et al. (*J Manag Care Spec Pharm.* 2021; 27(8):1118-1128). The observational retrospective cohort analysis utilized administrative claims data from two databases on more than 20,000 pediatric patients diagnosed with GHD. Approximately 68% of commercial patients and approximately 63% of Medicaid patients received daily growth hormone treatment, whereas approximately 32% of commercial patients and approximately 37% of Medicaid patients were untreated. In addition, mean adherence as measured by proportions of days covered, which is defined as the number of days covered by any daily growth hormone prescription during the follow-up period, was approximately 60% in the commercial cohort and approximately 50% in the Medicaid cohort. Only 32% of commercial and 18% of Medicaid patients reported adherence rates greater than 80%.

For adult patients with GHD, underdiagnosis and undertreatment are also a concern. Untreated adult GHD patients can experience reduced quality of life and increased risk of morbidity and mortality. In a retrospective observational study by Hoffman et al. (*Advances in Therapy, 2025;* 42(6):2853–2873) which analyzed electronic health records in the U.S. to identify patients with a high likelihood of adult GHD, 54,310 patients were identified as at risk for adult GHD, of which, only 3.1% were treated with growth hormone.

Since the introduction of hGH in 1981, a number of the world's largest pharmaceutical companies have developed and marketed daily-administered hGH products. All currently marketed daily hGH products in the United States – Norditropin® (Novo Nordisk A/S), Humatrope® (Eli Lilly and Company), Genotropin® (Pfizer Inc.), Zomacton® (Ferring Pharmaceuticals, Inc.) and Omnitrope® (Sandoz GmbH) – contain unmodified somatropin and are administered by subcutaneous injections. The global market for daily hGH products is largely composed of products from Novo Nordisk, Pfizer, Eli Lilly, Sandoz, and Merck KGaA, which together account for most of the global market share. However, according to the FDA drug shortage website, Humatrope has been discontinued due to a business decision which might impact the hGH global market share in the future.

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

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

- Unmodified somatropin: Two long-acting growth hormone products using encapsulation technologies previously received regulatory approval in the U.S. and Europe, but were subsequently discontinued due to commercial challenges. These include Nutropin Depot®, formerly marketed by Genentech, and Somatropin Biopartners, developed by LG Life Sciences and Biopartners GmbH. Nutropin Depot was approved by the FDA in 1999 and later withdrawn; Somatropin Biopartners (LB03002) was authorized by the EC in 2013, and later withdrawn. We believe that the lack of market acceptance was a result of the various safety and tolerability issues that tend to arise with encapsulation technologies.
- Permanent modification of growth hormone: Modification technologies prolong activity in the body by creating analogs of growth hormone through permanent modification of the growth hormone molecule. This modification may alter the molecular size and interaction with the growth hormone receptor and/or change the natural association affinity to endogenous proteins, as well as the distribution in the body. These changes may alter and reduce the efficacy of these drugs compared to unmodified daily somatropin and may also negatively impact the drug's safety.

Novo Nordisk received regulatory approval in various countries and regions including the U.S., Japan, and EU for once-weekly somapacitan (SOGROYA®) in adult and pediatric patients with GHD.

Pfizer (in collaboration with OPKO Health Inc.) received regulatory approval of once-weekly somatrogon (NGENLA™) in various countries and regions including the U.S., Japan, and EU for pediatric GHD.

A permanently PEGylated long-acting growth hormone developed by GeneScience Pharmaceuticals Co., Ltd. (Jintrolong®) is available in China for pediatric GHD, Turner syndrome and idiopathic short stature and the Somatropin Biopartners product (LB03002) is available in Korea. Other experimental growth hormone therapies based on permanent modification are in different stages of clinical development by various companies, including Genexine Inc., I-MAB, Amoytop, UnionGene, Anhui Anke Biotechnology, Alteogen, JCR Pharmaceuticals Co., Ltd., Kexing Biopharm, Qianhon Biopharma (Zonhon) and Evive Biotech (Yifan).

TransCon Growth Hormone (hGH)

TransCon hGH (lonapegsomatropin) is a prodrug composed of somatropin that is transiently bound to a TransCon carrier by a proprietary TransCon linker. TransCon hGH is administered once weekly and is designed to maintain the same mode of action as daily therapies by providing sustained release of active, unmodified somatropin, the same recombinant growth hormone molecule used in the daily hGH therapies that have historically been the standard of care.

TransCon Growth Hormone (hGH) for Pediatric and Adult GHD

TransCon hGH, marketed under the brand name SKYTROFA (lonapegsomatropin-tcgd), received regulatory approval in the U.S. for the treatment of pediatric patients one year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone, also known as GHD. SKYTROFA has been commercially available for prescription in the United States since October 2021. In the EU, Norway, Iceland, Liechtenstein, and Great Britain (covering England, Wales, Scotland), we received marketing authorization for TransCon hGH – known by its brand name SKYTROFA (lonapegsomatropin) – as a once-weekly subcutaneous injection for the treatment of children and adolescents aged 3 to 18 years with growth failure due to insufficient secretion of endogenous growth hormone. SKYTROFA has been commercially available for prescription in Germany since September 2023.

In July 2025, we announced that the FDA had approved SKYTROFA (lonapegsomatropin-tcgd; developed as TransCon hGH) for the replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD), a rare disorder resulting from decreased or total loss of growth hormone production. Further, on October 22,

2025, we announced commercial availability of SKYTROFA (TransCon hGH) in broader dosing ranges in the United States for the replacement of endogenous growth hormone in adults with growth hormone deficiency.

Clinical Trial of TransCon hGH in Japanese Pediatric GHD

In the ongoing Phase 3 riGHt Trial, we are evaluating TransCon hGH (N=15) compared to somatropin (N=16) as a treatment in Japanese children with GHD. The trial achieved its primary objective with Week 52 top-line results consistent with our pivotal heiGHt Trial and VISEN's Phase 3 trial. In the riGHt Trial, TransCon hGH was generally well tolerated with a safety profile that was similar to that of somatropin's. Trial subjects continue in the extension period.

Proprietary Auto-Injector

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

Figure: Our state-of-the-art auto-injector is designed to address important patient needs.

TransCon Growth Hormone (hGH) for Other Indications

In December 2024, we announced positive top-line results from the Phase 2 New InsiGHTS Trial. New InsiGHTS randomized and dosed 49 children with Turner syndrome aged 1 to 10 years old into one of four treatment groups 1:1:1:1 – one of three starting doses of TransCon hGH (0.24, 0.30, or 0.36 mg/kg/week) or an active comparator of daily somatropin with a starting dose of 0.35 mg/kg/week. Doses were individualized based on IGF-1. On the primary endpoint of annualized height velocity ("AHV") and secondary endpoint of change from baseline in height SDS, children treated with TransCon hGH demonstrated improved growth similar to daily somatropin at Week 26, independent of starting dose. As of December 31, 2025, 45 out of the 49 children are ongoing in the trial. TransCon hGH was generally safe and well tolerated, and with comparable safety and tolerability to daily somatropin, with four discontinuations from the trial for reasons unrelated to safety or efficacy of the study drug.

During the third quarter of 2025, we submitted the protocol for a basket trial evaluating additional growth disorder indications (planned for small for gestational age without catch-up growth; idiopathic short stature; SHOX deficiency (including Turner syndrome)). In addition, we are investigating potential combinations of TransCon hGH and TransCon CNP. For more information see the section entitled "Combination Therapy (TransCon CNP + TransCon hGH)."

Achondroplasia

Overview of Achondroplasia

Achondroplasia is a rare genetic condition arising from a systemic fibroblast growth factor receptor 3 ("FGFR3") variant, which causes serious muscular, neurological, and cardiorespiratory complications in addition to the well-characterized skeletal dysplasia that leads to disproportionate short stature. Achondroplasia is associated with a well-delineated range of clinical complications and manifestations, occurring in about one in 10,000 to 30,000 newborns or more than 250,000 worldwide. Achondroplasia results in severe skeletal complications and comorbidities including spinal stenosis due to premature fusion of the foramen magnum, sleep apnea, chronic ear infections, and muscular complications. Patients often face multiple surgeries to alleviate its many complications. There is significant unmet need for treatments that ameliorate complications and improve quality of life in achondroplasia.

Achondroplasia is caused by gain-of-function variants of the FGFR3 gene resulting in constitutive activation of FGFR3 that leads to an imbalance between the effects of the FGFR3 and C-type natriuretic peptide ("CNP") signaling . In achondroplasia, FGFR3 is constitutively activated, suppressing the differentiation of chondrocytes in the growth plate leading to poor endochondral bone growth and causing dysfunction in the skeletal muscle. Preclinical and clinical data show that therapeutic continuous CNP exposure helps to counteract the constitutively activated FGFR3 downstream.

In November 2021, BioMarin Pharmaceutical Inc.'s ("BioMarin") daily VOXZOGO® (vosoritide) was approved by the FDA to increase linear growth in pediatric patients with achondroplasia with open epiphyses. Additionally, BioMarin is developing a long-acting CNP product candidate.

BioMarin has initiated certain legal proceedings aimed at delaying or preventing patient access to TransCon CNP. We believe BioMarin's claims lack merit and that these actions threaten potential harm to patients by limiting or preventing access to a treatment option that has the potential to address multiple unmet clinical needs.

These legal proceedings include a case filed by BioMarin before the Unified Patent Court ("UPC") in Munich related to alleged infringement against EP3175863 (the "'863 patent"), along with a complaint filed with the U.S. International Trade Commission ("ITC") related to alleged infringement of U.S. Reissue Patent No. 48,267. Trial in the ITC is set for April 2026. In response to the ITC action, we initiated legal action before the District Court in the U.S. Northern District of California. The District Court litigation has been stayed in view of the pending ITC proceedings.

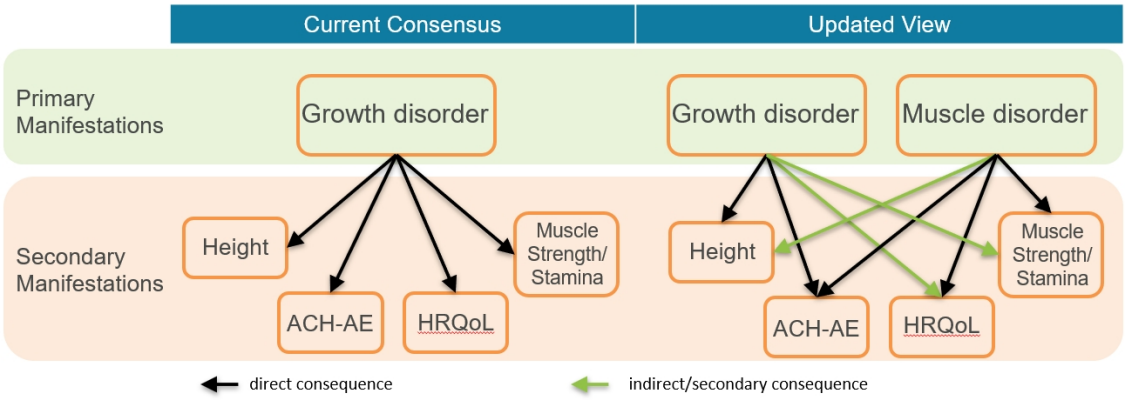
In the European case, we took the view that we did not infringe the '863 patent and that the patent was, in any event, invalid. Following opposition proceedings against the '863 patent that were initiated before the European Patent Office ("EPO") in September 2022, the EPO Technical Boards of Appeal revoked the '863 patent in its entirety on October 16, 2025. As a consequence of the revocation, the UPC dismissed the infringement case on December 29, 2025, which included an agreement for BioMarin to reimburse Ascendis for certain legal expenses related to the case. In addition, we have instituted proceedings before the Danish Maritime and Commercial High Court, claiming entitlement to European patent applications EP21211450.8, EP25151367.7 and EP25175852.0, all of which are divisional applications of the revoked '863 patent. The EPO has granted a stay of proceedings with respect to these divisional applications.

On June 12, 2025, BioMarin also submitted a Citizen Petition to the FDA under Section 505(q) of the Federal Food, Drug and Cosmetic Act requesting that FDA refrain from approving any analog of human CNP as a treatment for achondroplasia until orphan-drug exclusivities applicable to VOXZOGO expire. We submitted a response to the FDA in September 2025 and do not believe that our pending NDA for TransCon CNP (navepegritide) should be impacted by the Citizen Petition.

Also, on October 21, 2025, we filed a petition before the Korean Intellectual Property Trial and Appeal Board ("IPTAB") for the invalidation of BioMarin's Korean patent KR2033680.

Changing the Treatment Paradigm of Achondroplasia

Clinical manifestations of achondroplasia are associated with significant, potentially life-threatening complications and reduced quality of life. While achondroplasia has historically been considered a growth disorder, secondary manifestations beyond linear growth, including reduced muscle strength and stamina, suggest that achondroplasia is also a muscle disorder.



ACH-AE: Increased incidence of Achondroplasia-related Adverse Events.

HRQoL: Reduced Health-Related QOL; Height; Reduced height. Muscle Strength/Stamina; Reduced muscular functionality, including reduced strength and stamina.

TransCon CNP

TransCon CNP (navepegritide) is an investigational prodrug of CNP administered once weekly and designed to provide sustained release of active CNP supporting continuous exposure for the treatment of achondroplasia. TransCon CNP is designed to provide effective shielding of CNP from neutral endopeptidase degradation in subcutaneous tissue and the blood compartment, minimize binding of CNP to the NPR-C receptor to decrease clearance, and release unmodified CNP (89-126), which is small enough in size to allow effective penetration into growth plates. Shorter-acting CNP and CNP analogs in development have resulted in high maximum serum concentration ("C_{max}") levels that may cause adverse hypotensive events. We believe the therapeutically sustained release of TransCon CNP offers advantages that may mitigate this issue, leading to continuous CNP exposure while avoiding a high C_{max} to correlate with better therapeutic outcomes.

TransCon CNP for the Treatment of Achondroplasia

We submitted a New Drug Application ("NDA") for the treatment of children with achondroplasia on March 31, 2025 and the FDA has accepted for priority review our NDA for TransCon CNP (navepegritide). As a result of further information from the Company submitted to the FDA on November 5, 2025, related to the post-marketing requirement in response to the FDA's ongoing review of the NDA, the FDA has set a Prescription Drug User Fee Act ("PDUFA") goal date of February 28, 2026 to complete its review. In addition, we submitted a Marketing

Authorisation Application ("MAA") to the European Medicines Agency ("EMA") for the treatment of children with achondroplasia on October 8, 2025.

In February 2019, we were granted ODD by the FDA for TransCon CNP for the treatment of achondroplasia. In July 2020, we received ODD from the EC for TransCon CNP for the treatment of achondroplasia.

Clinical Development of TransCon CNP for Achondroplasia

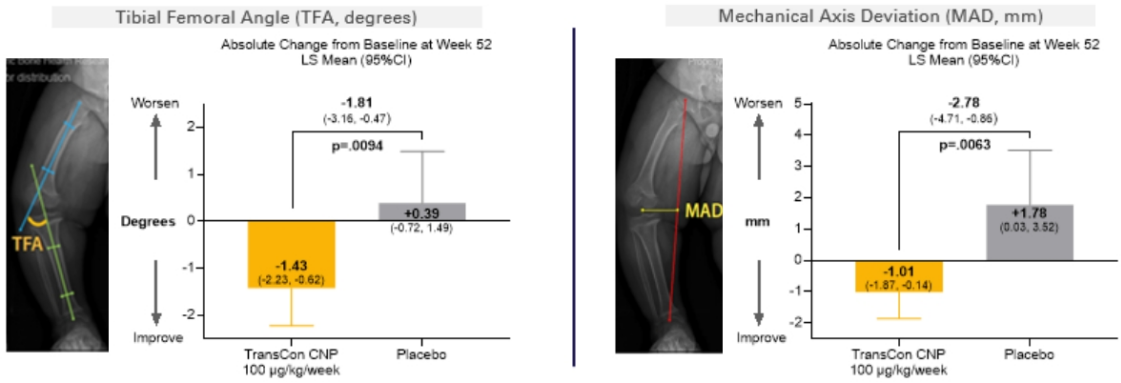
Our pivotal ApproaCH Trial, our Phase 2 ACcomplisH Trial, and our long-term extension trial AttaCH, are evaluating the safety and efficacy of TransCon CNP in children with achondroplasia. The reACHin Trial is evaluating the safety, tolerability, and efficacy of TransCon CNP in infants with achondroplasia (aged 0 to < 2 years at the time of randomization). The teACH Trial is evaluating the safety, tolerability, and efficacy of TransCon CNP in adolescents with achondroplasia (aged 12 to 18). As of December 31, 2025, 80 children who completed the ApproaCH trial have rolled over into the AttaCH open-label extension trial and are all continuing treatment in the extension trial.

In November 2025, we announced that Week 52 results from the pivotal ApproaCH trial were published in *JAMA Pediatrics* titled "Once-Weekly Navepegritide in Children with Achondroplasia: The ApproaCH Randomized Clinical Trial." The authors reported that treatment with TransCon CNP led to significantly higher annualized growth velocity (AGV) at Week 52 compared to placebo (primary endpoint), as well as improved lower limb alignment and body proportionality and positive changes in health-related QOL, with a safety and tolerability profile similar to placebo. The publication is available at Savarirayan R, et al. *JAMA Pediatr*. 2026;180(1):18-25. doi:10.1001/jamapediatrics.2025.4771.

In September 2025, we announced new analyses from the pivotal ApproaCH Trial were presented at the American Society for Bone and Mineral Research (ASBMR) Annual Meeting. The new analyses showed that children treated with TransCon CNP had improvements in the Physical Functioning domain of the Achondroplasia Child Experience Measure (ACEM-PF), with greatest benefits in younger children who had more severe genu varum (≥5°) at baseline, supporting benefits beyond linear growth. Further analyses showed correlations between improvements in physical functioning and improvements in lower limb alignment in these children, supporting the potential for TransCon CNP to provide benefits beyond linear growth.

In May 2025, we announced data demonstrating improvements in growth and bone morphometry from Week 52 of our pivotal ApproaCH Trial of TransCon CNP (navepegritide) in children with achondroplasia. TransCon CNP demonstrated superiority over placebo in annualized growth velocity (AGV), with a safety and tolerability profile comparable to placebo that included a low rate of injection site reactions, no treatment-related serious adverse events (SAEs), no cases of symptomatic hypotension, no fractures, and no acceleration of bone age versus chronological age. Analyses also showed that TransCon CNP improved aspects of bone morphometry at Week 52. This included improvement in lower limb alignment and proportional growth, as well as increases in spinal canal dimensions, versus placebo.

In January 2025, we announced data demonstrating improvements in leg bowing, a common complication in achondroplasia, observed with TransCon CNP compared to worsening observed with placebo in the pivotal ApproaCH Trial.



In September 2024, we announced top-line data from ApproaCH, a pivotal, multicenter, randomized, double-blind, placebo-controlled trial of once-weekly TransCon CNP versus placebo in 84 children (aged 2 to 11 years) with achondroplasia. Participants were randomized 2:1 to receive TransCon CNP 100 µg/kg/week or placebo for 52 weeks in the double-blind period, after which all participants could choose to receive TransCon CNP at the 100 µg/kg/week dose in an ongoing open-label extension. In the trial, children treated with once-weekly TransCon CNP demonstrated annualized growth velocity ("AGV") superior to those treated with placebo. TransCon CNP also demonstrated statistically significant improvements in other growth parameters, including height Z-score and change from baseline AGV.

Highlights of the ApproaCH Trial Top-line Data

Primary Endpoint

- For the primary endpoint of AGV at Week 52, children treated with TransCon CNP (n=57) demonstrated an LS mean AGV of 5.89 cm/year compared to 4.41 cm/year in the placebo arm (n=27), an LS mean difference of 1.49 cm/year ($p<0.0001$).
- Sub-group analyses:
  - Children aged 2 to <5 years treated with TransCon CNP (n=21) demonstrated an LS mean AGV at Week 52 of 6.07 cm/year compared to 5.06 cm/year in the placebo arm (n=10), an LS mean difference of 1.02 cm/year ($p=0.0084$).
  - Children aged 5-11 years treated with TransCon CNP (n=36) demonstrated an LS mean AGV at Week 52 of 5.79 cm/year compared to 4.02 cm/year in the placebo arm (n=17), an LS mean difference of 1.78 cm/year ($p<0.0001$).

AGV Change from Baseline

- Children aged 2 to <5 years, treated with TransCon CNP (n=19) demonstrated a change from baseline AGV at Week 52 of 1.57 cm/year compared to 0.43 cm/year in the placebo arm (n=10), an LS mean difference of 1.15 cm/year ($p=0.0047$).
- Children aged 5-11 years, treated with TransCon CNP (n=35) demonstrated a change from baseline AGV at Week 52 of 2.29 cm/year compared to 0.52 cm/year in the placebo arm (n=17), an LS mean difference of 1.78 cm/year ($p<0.0001$).

Secondary Endpoints

- For the secondary endpoint of change in achondroplasia-specific height Z-score, children treated with TransCon CNP (n=57) demonstrated an LS mean change from baseline achondroplasia-specific height Z-score of 0.30 compared to 0.01 in the placebo arm (n=27), an LS mean difference of 0.28 ($p<0.0001$).
- For the secondary endpoint of change in CDC-based height Z-score, children treated with TransCon CNP (n=55) demonstrated an LS mean change from baseline CDC Height Z-score of 0.15 compared to -0.15 in the placebo arm (n=27), an LS mean difference of 0.30 (p=0.0003).

Safety Results Summary

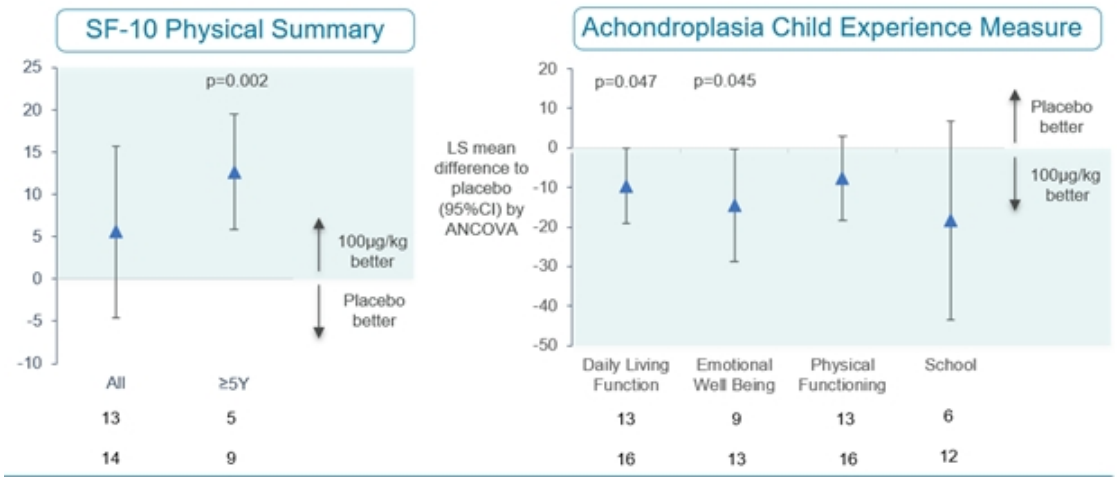
- TransCon CNP was generally well-tolerated and demonstrated safety profile similar to that observed in the placebo arm, with generally mild treatment emergent adverse events ("TEAEs"), no evidence of hypotensive effect, and a low frequency of injection site reactions (0.41 events per patient year), all mild.
- No adverse events ("AEs") led to discontinuation of TransCon CNP or withdrawal from the trial and no serious adverse events ("SAEs") were assessed as related to TransCon CNP.

In December 2023, we announced new analyses demonstrating benefits beyond linear growth from the blinded and ongoing OLE periods of ACcomplisH, a Phase 2 randomized, double-blind, placebo-controlled, dose-escalation trial of TransCon CNP in children aged 2 to 10 years with achondroplasia. In the trial, all 57 patients have now completed one year of treatment with TransCon CNP at 100 µg/kg/week, the dose agreed with regulatory agencies for the active arm in our pivotal ApproaCH Trial.

We analyzed available data for patients who only received TransCon CNP at the 100 µg/kg/week dose in either the blinded or OLE period and were treated for one year (n=19), compared to those administered placebo for one year (n=15). Results showed that these TransCon CNP-treated patients (data available for 9-16 patients) showed improvements (nominal p-value <0.05) in health-related QoL and disease impacts compared to those receiving placebo (data available for 5-13 patients).

Assessments were performed with the SF-10 (a 10-item non-disease specific survey of a child's functional health and well-being that has been validated to assess children aged 5 years and older) and the Achondroplasia Child Experience Measure ("ACEM") a condition-specific clinical outcome measure that assesses the impact of achondroplasia on a child's health-related QOL, with statistically significant improved outcome in TransCon CNP-treatment versus placebo for:

- SF-10 Physical Summary (p=0.002, aged 5 years and older)
- ACEM Daily Living Function (p=0.047)
- ACEM Emotional Well-being (p=0.045)



The 46 children switching from placebo or a lower dose of TransCon CNP to the 100 µg/kg/week dose in the OLE demonstrated improved growth after one year of treatment, similar to the growth benefits seen in the 11 children treated with 100 µg/kg/week in the one-year randomized, double-blind period of ACcomplisH.

The 46 children switching from placebo or a lower dose of TransCon CNP to the 100 µg/kg/week dose in the OLE demonstrated improved growth after one year of treatment, similar to the growth benefits seen in the 11 children treated with 100 µg/kg/week in the one-year randomized, double-blind period of ACcomplisH.

During the third quarter of 2023, we filed an Investigational New Drug Application amendment with the FDA to initiate reACHin, a Phase 2, multicenter, double-blind, randomized, placebo-controlled trial, designed to evaluate the safety, tolerability, and efficacy of 100 µg/kg of TransCon CNP once-weekly for 52 weeks in infants with achondroplasia, aged 0 to < 2 years at the time of randomization.

In November 2022, we announced top-line results from ACcomplisH, a Phase 2 randomized, double-blind, placebo-controlled, dose-escalation trial evaluating the safety and efficacy of once-weekly TransCon CNP compared to placebo in children with achondroplasia aged 2 to 10 years old.

The ACcomplisH Trial evaluated 57 children with achondroplasia aged 2 to 10 years old, randomized in a 3:1 ratio to receive either sequential ascending doses of once-weekly TransCon CNP (6 µg/kg/week, 20 µg/kg/week, 50 µg/kg/week, 100 µg/kg/week) or placebo for 52 weeks. The trial met its primary objectives, demonstrating that TransCon CNP at 100 µg/kg/week (n=11) was superior to placebo (n=15) on the primary efficacy endpoint of AGV at 52 weeks (p=0.0218).

The ACcomplisH Trial completed in October 2024, with 55 of the original 57 children transitioning into AttaCH (n=53) a multicenter, long-term, open-label extension trial to continue treatment with TransCon CNP 100 µg/kg/week, and into COACH (n=2), a TransCon CNP and TransCon hGH combination therapy trial. Two children did not roll-over for reasons unrelated to safety or efficacy of the study drug. For more information, see section entitled, “Combination Therapy TransCon CNP + TransCon hGH.”

As of December 31, 2025, 53 children continue in AttaCH with three children withdrawn from treatment, for reasons unrelated to safety or efficacy of the study drug. Seven (n=7) children from AttaCH were enrolled and continue in COACH. There have been no withdrawals from COACH.

In 2019, we initiated the ACHieve Study, a five-year, multi-center natural history study designed to gain insight into the experiences of pediatric patients with achondroplasia. ACHieve was designed to evaluate growth velocity, body proportionality, and comorbidities over time in children with achondroplasia up to eight years old. No study medication was administered in the ACHieve Study. The study ended in the first quarter of 2024.

Combination Therapy (TransCon CNP + TransCon hGH)

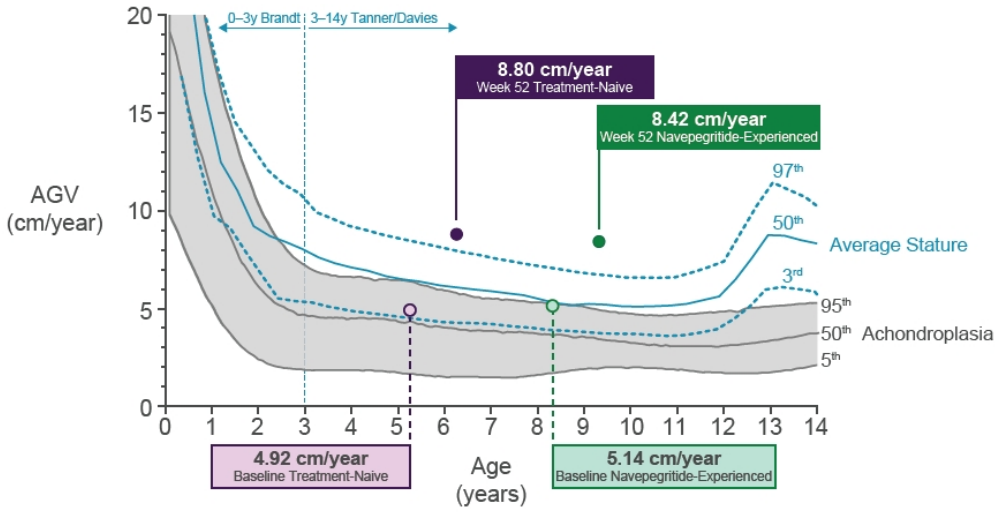
TransCon CNP has demonstrated improvement in linear growth and in benefits beyond height. Clinical use of daily growth hormone monotherapy has demonstrated some growth improvements in children with achondroplasia; however, without reports of benefits beyond height, as it does not address the underlying overactive FGFR3 signaling pathway.

We believe the combination of once-weekly TransCon CNP and TransCon hGH, through two independent and complementary mechanisms of action, may provide benefits beyond monotherapies in achondroplasia. The active CNP released from TransCon CNP continuously relieves the pre-hypertrophic block in the growth plate, enabling the strong complementary effect of unmodified somatropin released from TransCon hGH.

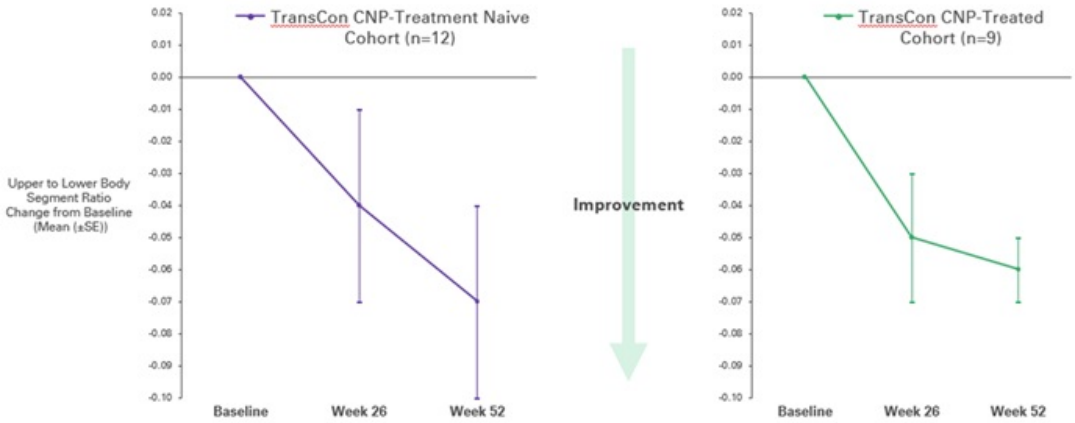
COACH, a Phase 2 open-label single-arm trial is the first clinical trial to evaluate combination treatment with once-weekly investigational TransCon CNP (navepegritide) and once-weekly TransCon hGH (lonapegsomatropin) in children with achondroplasia (age 2 to 11 years). The primary objective is to evaluate the treatment effect on linear growth and safety. Secondary objectives are to evaluate treatment effect on quality of life, radiological endpoints, physical functioning, and body composition. The trial enrolled 21 children (treatment naïve, n=12; prior treatment with TransCon CNP (100 µg/kg/week) for at least 1 year, n=9).

In January 2026, we announced topline results from Week 52 of COACH, the first Phase 2 clinical trial to evaluate combination therapy with once-weekly TransCon CNP (navepegritide) and once-weekly TransCon hGH (lonapegsomatropin) in children with achondroplasia. Annualized growth velocity exceeded the 97th percentile of average stature children and the improvement in achondroplasia-specific height Z-score indicated a tripling of efficacy compared to TransCon CNP monotherapy. Additionally, combination therapy demonstrated benefits beyond linear growth with improvements in body proportionality and arm span, aligning with the increase in linear growth. The combination therapy was generally well tolerated, with generally mild TEAEs, consistent with TransCon CNP and TransCon hGH monotherapies.

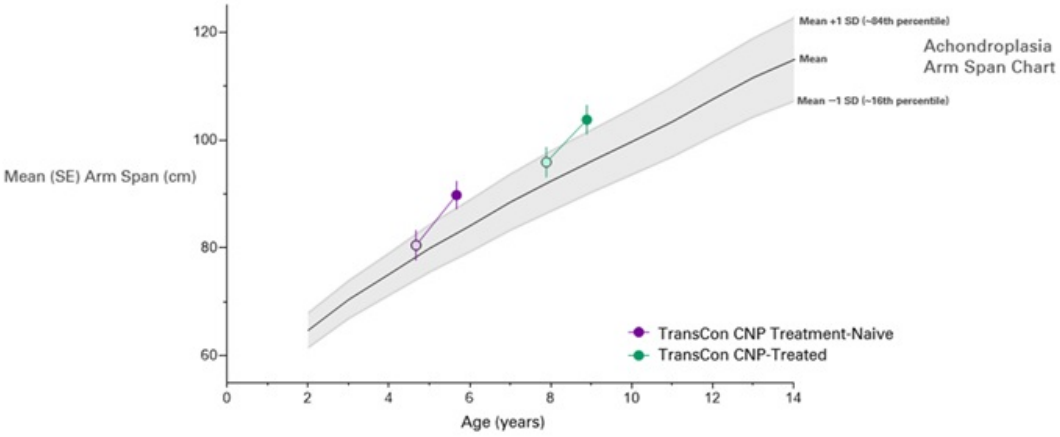
At week-52, the mean AGV with TransCon CNP and TransCon hGH combination treatment continued to exceed the 97th percentile of average-stature children.



At week-52, TransCon hGH + TransCon CNP treatment demonstrated accelerated improvement in body proportionality, aligning with the increase in linear growth.



At week-52, arm span of children treated with combination therapy improved beyond the 84th-percentile of children with achondroplasia.



TransCon Product Candidates—Oncology

Market Opportunity in Oncology

Cancer continues to be one of the leading causes of mortality. Improved understanding of the cellular and molecular mechanisms involved in anti-tumor immune responses has fueled the rapid growth of immuno-oncology therapeutics. Immune checkpoint inhibitors, such as anti-PD-(L)1 and anti-CTLA-4 antibodies, have provided new therapeutic options for patients.

Despite recent advances, a high need for new treatment options remains for patients who do not respond to, or who respond inadequately to, current therapies. In addition to insufficient efficacy, many current treatments are limited by toxicities that result in dose reductions, treatment discontinuations, or long-term health risks to patients.

We believe that one approach to potentially improve efficacy while limiting adverse events is to create long-acting product candidates using our sustained systemic release TransCon technology, allowing for more consistent circulating drug levels and potentially avoiding high peak concentrations that are often associated with toxicity.

We are currently developing TransCon technology in oncology for a variety of solid tumors, with encouraging early data in HER2+ breast cancer, platinum resistant ovarian cancer and melanoma. Aside from Proleukin being the only approved IL-2, TransCon IL-2 b/g may face competition from other IL-2 type drug candidates in development, including those being developed by Anaveon, Asher Bio, Aulos, Dragonfly, GI Innovation, Hanmi Pharmaceutical, Innovent, Medicenna, Roche, Synthekine, and Werewolf. In addition, TransCon IL-2 b/g may face competition from drug candidates in development for platinum resistant ovarian cancer, including Astra Zeneca, Corcept, Daiichi Sankyo, Eli Lilly, Genelux, Genmab, and Merck. In melanoma, TransCon IL-2 b/g may face competition from drug candidates in development including from Immatics, Immunocore, Innovent, Replimune, Regeneron, and Philogen.

TransCon Technologies for Oncology

We believe prolonging the therapeutic activity and targeting the drug activity to the relevant cell types and tissues have the potential to improve treatment outcomes. We believe TransCon is well-suited to improve cancer treatments given the large number of validated targets with known limitations. By applying our unique algorithm for product innovation to clinically validated targets and pathways, we believe TransCon has the potential to improve outcomes currently limited by suboptimal efficacy and systemic toxicity.

We believe TransCon technologies may have the potential to increase the efficacy of small molecules, peptides and proteins without increasing toxicity, which could offer the potential to treat more patients with new combinations and multi-agent regimens that would not otherwise be feasible.

We are currently investigating one clinical-stage product candidate designed to activate the patient's own immune system to eradicate malignant cells. We believe our approach, if successfully developed, has the potential to improve the efficacy of systemically administered, clinically validated therapies while limiting adverse effects.

Our early clinical and nonclinical studies have shown sustained activation of cytotoxic immune cells that resulted in robust anti-tumor responses by TransCon product candidates using infrequent administration.

TransCon IL-2 b/g for Sustained Systemic Release

TransCon IL-2 b/g (onvapegleukin alfa) is an investigational long-acting prodrug designed to improve cancer immunotherapy through sustained release of an IL-2 variant that selectively activates IL-2 b/g, with minimal binding to IL-2Rα. The IL-Believe Trial, a Phase 1/2 clinical trial to evaluate the safety and efficacy of TransCon IL-2 b/g in locally advanced or metastatic solid tumors, alone or in combination with pembrolizumab or other anti-cancer therapies, has completed dose escalation and is enrolling patients in multiple indication-specific dose expansion cohorts, including platinum-resistant ovarian cancer ("PROC"), melanoma, and HER2+ breast cancer.

In October 2025, we reported updated results at the European Society for Medical Oncology ("ESMO") that further indicate clinical activity in late-line patients with PROC treated with TransCon IL-2 b/g with weekly paclitaxel (Cohort 3, 3SK, and 14 in the IL-Believe Trial). As of data cutoff date of September 2, 2025, 70 patients (median 4 prior lines of therapy; 67% previously treated with at least 2 lines of taxane-containing therapy) were enrolled and 53 were efficacy-evaluable to-date, with 7 pending first post-baseline scan. Clinical responses were observed in 25% (13/53) of patients who had received two to ten prior lines of therapy (three confirmed and ten unconfirmed responses, with six of the unconfirmed continuing on study treatment). Data continued to suggest that TransCon IL-2 b/g in combination with weekly paclitaxel is generally well-tolerated with the majority of TransCon IL-2 b/g-related TEAEs being grade 1 or 2 in severity.

TransCon IL-2 b/g induced significant peripheral expansion of cytotoxic CD8+ T cells and natural killer cells with minimal expansion of regulatory T cells, despite concurrent chemotherapy. Proliferating antigen-experienced PD-1+CD8+ T cells expanded significantly at 1 week post dose. Expanded PD-1+CD8+ T cells predominantly exhibited stem-like or transitory states, with limited progression to terminally differentiated or exhausted phenotypes. In addition, clinical responses significantly correlated with peripheral CD8+ T cell expansion in PROC. Furthermore, significant increase in CD8+ T cells was observed in the tumor of paired on-treatment biopsies from all available paired pre-treatment and on-treatment tumor samples from IL Believe Trial as of September 2, 2025, dosed at 80 (n=2) or 120 μg/kg (n=11).

We expect to provide median overall survival ("OS") data for this cohort of 70 patients in the second quarter of 2026 as the dataset continues to mature.

In September 2024, we announced initial data showing signs of clinical activity in heavily pre-treated patients with PROC treated (cohort 3) with TransCon IL-2 b/g in combination with chemotherapy in the ongoing Phase 1/2 IL-Believe Trial of TransCon IL-2 b/g. As of a cutoff date of July 29, 2024, of the 18 patients (median age 64 years) included in the initial assessment, 14 were efficacy evaluable patients who had one or more post-baseline tumor assessment(s), plus an additional four who discontinued treatment before the first post-baseline tumor assessment due to disease progression or death.

As of the data cutoff, clinical responses were observed in 29% (4/14) of the efficacy evaluable patients (two confirmed and two unconfirmed partial responses in patients who had received three to seven prior lines of treatment – including patients whose disease had previously progressed on mirvetuximab soravtansine-gynx), suggesting the potential for clinical activity in heavily pre-treated patients. The data suggest that TransCon IL-2 b/g was generally well-tolerated: the most common TEAEs related to combination therapy with TransCon IL-2 b/g plus chemotherapy were fatigue, thrombocytopenia, neutropenia, and anemia. Most TransCon IL-2 β/γ-related TEAEs were grade 1 or 2.

In June 2024, we reported updated results from our ongoing Phase 1/2 IL-Believe Trial of TransCon IL-2 b/g. Data included the first presentation of Phase 2 dose expansion Cohort 4 (TransCon IL-2 b/gin combination with TransCon TLR7/8 Agonist) in post anti-PD-1 melanoma and new analyses of patients from dose escalation cohorts with prior disease progression on checkpoint inhibitors, along with biomarker studies correlating cytotoxic immune cell expansion and observed clinical benefit. As of the April 16, 2024 data cutoff, confirmed clinical partial responses were observed in 40% (two out of five) of efficacy-evaluable patients from Cohort 4, suggesting potential synergy of our two novel immunotherapy candidates in patients who did not derive sufficient benefit from checkpoint inhibitors. Of efficacy-evaluable patients with prior disease progression on checkpoint inhibitors to date (from Phase 1 dose escalation cohorts) in the IL-Believe Trial, confirmed clinical responses (per RECIST v1.1) were observed in 45% (five out of eleven) administered TransCon IL-2 b/g doses ≥80 µg/kg every 3 weeks, suggesting clinical benefit in treatment-resistant settings (monotherapy (n=4): 1 confirmed partial response ("PR") in colorectal cancer; combination with pembrolizumab (n=2): 1 confirmed complete response and 1 confirmed PR in small-cell lung cancer; combination with TransCon TLR7/8 Agonist (n=5): 2 confirmed PRs in melanoma). In this trial, TransCon IL-2 b/g alone or in combination with pembrolizumab or TransCon TLR7/8 Agonist was generally well tolerated with no new safety signals.

In October 2023, we announced updated data from the ongoing Phase 1 dose escalation cohort from IL-Believe Trial. Forty-six patients were enrolled into dose escalation cohorts: 25 to monotherapy and 21 to combination therapy. As of the August 15, 2023, data cutoff, anti-tumor clinical responses were observed with TransCon IL-2 b/g monotherapy (colorectal cancer with PR) or in combination with pembrolizumab (small cell lung cancer, one with confirmed PR and one ongoing with unconfirmed complete response) in heavily pre-treated patients who previously progressed on checkpoint inhibitors. TransCon IL-2 b/g every three weeks was generally well-tolerated, with no meaningful effect on Tregs and eosinophils.

In September 2023, we announced completion of Phase 1 dose escalation in combination with pembrolizumab of the IL-Believe Trial with a total of 21 patients enrolled and recommended Phase 2 dose ("RP2D") determined at 120 µg/kg IV every three weeks. Twenty-one patients were enrolled.

In May 2023, we announced completion of the Phase 1 monotherapy dose escalation of the IL-Believe Trial with RP2D determined at 120 µg/kg IV every three weeks with 25 heavily pre-treated patients enrolled and a median of four prior lines of systemic therapies.

Strategic Collaborations and Investments

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

Novo Nordisk A/S

In November 2024, we entered into a research and development collaboration and license agreement with Novo Nordisk pursuant to which we granted Novo Nordisk an exclusive worldwide license to the TransCon technology platform to develop, manufacture and commercialize Novo Nordisk proprietary products (including Semaglutide) in metabolic diseases (including obesity and type 2 diabetes) and a product-by-product exclusive license in cardiovascular diseases.

The agreement includes provisions requiring at least one TransCon Semaglutide product and at least one other TransCon technology-based product to be identified, developed and commercialized in metabolic diseases to maintain certain exclusivities in the field, with additional provisions for cardiovascular diseases. Under the terms of the agreement, Novo Nordisk also receives exclusive rights to expand any resulting metabolic disease products into other therapeutic areas. The lead program in the collaboration is a once-monthly TransCon Semaglutide product candidate that will initially target obesity and type 2 diabetes.

Under the agreement, we have the potential to receive total payments of up to $285 million in upfront, development and regulatory milestone payments for the lead program. In addition, we have the potential to receive sales-based milestone payments and tiered royalties on global net sales. The $285 million includes an upfront fee of $100 million for the exclusive license that was paid to us in January 2025. For each additional metabolic or cardiovascular disease product candidate, we are eligible to receive payments of up to $77.5 million in development and regulatory milestone payments. In addition, we have the potential to receive sales-based milestone payments and tiered royalties on global net sales. Novo Nordisk agreed to pay royalties for each potential licensed product developed under the agreement that are an escalating tiered, mid-single digit percentage of the annual net sales of such licensed product and are subject to reduction due to patent valid claim expiration, biosimilar product market share, payment made under certain licenses for third party intellectual property and Inflation Reduction Act price negotiations.

Under the agreement, we have agreed to conduct certain pre-agreed early research and development of TransCon product candidates under the collaboration and we are eligible to receive cost reimbursement from Novo Nordisk for its performance of such research and development activities under the agreement with respect to such TransCon product candidates. Novo Nordisk is responsible for any other non-clinical and clinical development, regulatory, commercial manufacturing, and commercialization of such TransCon product candidates, and all costs associated with such activities.

Subject to the terms of the agreement, we granted Novo Nordisk an exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses, to use its proprietary TransCon technology platform to develop, manufacture and commercialize Novo Nordisk proprietary products in metabolic diseases (including obesity and type 2 diabetes) and a product-by-product exclusive license in cardiovascular diseases. Additionally, we granted Novo Nordisk an exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses, to use its proprietary TransCon technology platform to develop, manufacture and commercialize GLP-1 receptor products using the TransCon technology for all indications, except for (i) certain pre-agreed rare endocrine indications, (ii) all indications in respect of the eye and adnexa and (iii) all indications in respect of oncology.

Until expiry of the last royalty term and for one-year thereafter, we are not permitted to research, develop, manufacture, commercialize, or otherwise exploit outside of the collaboration, any GLP-1 receptor product or any other licensed products that have been subject to the collaboration. We are also not permitted to undertake any research, development, manufacture, commercialization, or other exploitation of products outside of the collaboration in the metabolic field until expiry of the last royalty term of any licensed products that have been subject to the collaboration in metabolic diseases.

Unless earlier terminated, the agreement has a royalty term that continues, on a per licensed product and per country basis, until the later of (i) the expiration of the last valid patent claim for any of our patents, joint improvement patents, licensed product patents as well as any improvements made by Novo Nordisk covering the licensed product's dosage regimen or target product profile, or (ii) 11 years after the first commercial sale of such licensed product in such country.

Novo Nordisk has the right to terminate the agreement without cause in its entirety or on a per licensed product basis. We have the right to terminate the agreement in its entirety in case Novo Nordisk brings patent challenges with respect to our patents. The agreement may also be terminated by either party based on an uncured material breach by the other party or the bankruptcy of the other party.

Upon termination of the agreement due to Novo Nordisk's default, some or all of the licenses granted by us to Novo Nordisk to develop, manufacture and commercialize any of the licensed products will automatically terminate.

Upon termination of the agreement due to certain defaults by us, Novo Nordisk may choose to either (i) have the license granted by us to Novo Nordisk to develop, manufacture and commercialize licensed products terminate in its entirety or on a product-by-product basis; or (ii) continue with respect to the affected licensed product at a reduced payment rate.

In January 2025, we announced that our multi-product collaboration with Novo Nordisk for TransCon technology-based therapies in obesity and metabolic diseases continues and that the lead program TransCon Semaglutide, remains on track to enter the clinic as anticipated.

Teijin Limited

In November 2023, we announced that we entered into an exclusive license agreement with Teijin for the further development and commercialization of TransCon hGH, TransCon PTH, and TransCon CNP for endocrinology rare disease in Japan. Under the terms of the agreement with Teijin, we received an upfront payment of $70 million, with additional development and regulatory milestones of up to $175 million, transfer pricing and commercial milestones. In addition, we are eligible to receive royalties on net sales in Japan, of up to a mid-20's percentage, varying by product.

In November 2025, Teijin announced that YORVIPATH is commercially available for prescription.

VISEN Pharmaceuticals

In November 2018, we announced the formation of VISEN, a company established to develop and commercialize our endocrinology rare disease therapies in Greater China. In connection with the formation of VISEN, we granted VISEN exclusive rights to develop and commercialize certain product candidates based on our proprietary TransCon technologies, including TransCon hGH, TransCon PTH, and TransCon CNP, in Greater China for use in all human indications, subject to certain exceptions. As consideration for the rights granted to VISEN, we received 50.0% ownership in the outstanding shares of VISEN and concurrently with the rights we granted to VISEN, entities affiliated with Vivo Capital and Sofinnova Ventures purchased shares in VISEN for an aggregate purchase price of $40 million in cash. In January 2021, we invested an additional $12.5 million in VISEN as part of VISEN's $150 million Series B financing.

On March 20, 2025, VISEN announced the pricing of its initial public offering ("IPO") on the Hong Kong Stock Exchange. The shares offered in the IPO were priced at HKD 68.80 per share and expected to result in gross proceeds of HKD 783,288,000 (approximately USD 100 million) plus a potential greenshoe of up to HKD 117,489,760 (approximately USD 15 million). This amount was calculated before deducting underwriting discounts, commissions, and other offering expenses. The IPO closed on March 21, 2025, and VISEN's shares began trading under the stock code 2561.HK. Ascendis Pharma holds 41,136,364 shares in VISEN. Following the IPO, the Company owned 39.2% in VISEN. The management and existing shareholders of VISEN, including Ascendis Pharma, have entered into customary lock-up agreements restricting the sale of VISEN shares for six months following the IPO; additionally, certain significant shareholders of VISEN, including Ascendis Pharma, are subject to an additional lock-up obligation during the period commencing on the date that is six months after the IPO and ending on the date that is 12 months after the IPO during which such shareholders may not sell shares of VISEN to an extent that would cause such shareholder to cease being a controlling shareholder of the VISEN pursuant to applicable listing rules. As of December 31, 2025 and 2024, the Company's ownership in VISEN was 39.2% and 43.9%, respectively. As of December 31, 2025, VISEN's share price at the Hong Kong Stock Exchange was HK$32.80, reflecting the market value of the Company's equity position of €147.5 million.

In January 2026, VISEN announced its biologics license application ("BLA") for lonapegsomatropin (TransCon hGH) was approved by the National Medical Products Administration ("NMPA") of China for the treatment of pediatric patients who have growth failure due to inadequate secretion of growth hormone in China.

In September 2025, VISEN announced that palopegteriparatide (TransCon PTH) was approved by the Hainan Medical Products Administration for clinical use in the Boao Lecheng Pilot Zone for the treatment of adults with chronic hypoparathyroidism.

In August 2024, VISEN announced top-line data from the 26-week randomized, double-blind, placebo-controlled portion of the Phase 3 PaTHway China Trial of Palopegteriparatide (TransCon PTH) in adults with chronic hypoparathyroidism. VISEN reported a statistically significant higher proportion of patients treated with palopegteriparatide achieved the primary multi-component endpoint compared to placebo. The primary multi-component endpoint was achieved by 77.6% of palopegteriparatide-treated patients (45 of 58), compared to 0.0% of patients (0 of 22) in the placebo group (p-value <0.0001). Results were consistent with those announced by us for its palopegteriparatide Phase 3 trial.

In November 2023, VISEN announced top-line results from the Phase 2 ACcomplisH China Trial in children with achondroplasia aged 2 to 10 years. VISEN reported that patients dosed with TransCon CNP at the 100 μg CNP/kg/week showed significantly higher AGV than placebo at Week 52.

In November 2022, VISEN announced data from its pivotal Phase 3 study of TransCon hGH in children with GHD in China. VISEN reported that patients dosed with TransCon hGH demonstrated an AHV of 10.66 cm/year compared to 9.75 cm/year for the daily hGH at 52 weeks (treatment difference at 0.91 cm/year with a 95 percent confidence interval: 0.37 – 1.45 cm/year, p=0.0010), reaching its primary objective, demonstrating that TransCon hGH is non-inferior to the daily hGH.

Market Opportunity in China

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

The purpose of our investment in VISEN is to support our strategy to extend our endocrinology rare disease portfolio globally and establish a presence in China in partnership with collaborators who have significant experience and knowledge of the biopharmaceutical opportunity in China.

Rights Agreements

Under three exclusive license agreements, each effective November 7, 2018, and as amended January 4, 2021, between the Company and VISEN (collectively, the "Rights Agreements"), VISEN must use diligent efforts to develop and commercialize licensed products in Greater China. Additionally, we and VISEN will conduct certain research and development activities allocated to the respective party under a research and technical development plan, and VISEN will reimburse us for costs of conducting such activities, including costs of our personnel committed to performing such activities in Greater China.

We entered into a clinical supply agreement with VISEN in 2018 to provide product supply for use in conducting clinical trials in Greater China. Additionally, during 2023, we entered into a commercial supply agreement governing commercial supply of licensed product (TransCon hGH) to VISEN on the terms and conditions set forth in the Rights Agreements. Further, in June 2025, we entered into a Commercial Supply Framework Agreement with VISEN regarding the supply of additional batches of licensed product (TransCon hGH) to VISEN.

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

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

Eyconis, Inc

In January 2024, we announced the formation and launch with Frazier Life Sciences of Eyconis, a separate company created to develop, manufacture, and commercialize TransCon ophthalmology assets globally, together with a $150 million commitment from an investor syndicate that included Frazier, RA Capital Management, venBio, and HealthQuest Capital. We have granted Eyconis exclusive rights to develop and commercialize TransCon ophthalmology products globally and received an equity position in the newly formed company. In addition, we are eligible to receive development, regulatory, and sales milestone payments, plus single digit royalties on global net sales of commercialized products, if any. As of December 31, 2025 and 2024, the Company's ownership in Eyconis was 33.2% and 41.6%, respectively.

Manufacturing

As we do not maintain the capability to manufacture finished drug products, we utilize contract manufacturers to manufacture finished drug product of our proprietary TransCon products and product candidates intended for commercial or clinical use. We source starting materials for our manufacturing activities from one or more suppliers. For the starting materials necessary for our proprietary TransCon product candidate development, we have agreements for the supply of such starting materials with drug manufacturers or suppliers that we believe have sufficient capacity to meet our demands. However, from time to time, we source critical raw materials and services

from one or a limited number of suppliers and there is a risk that if such supply or services were interrupted, it would materially harm our business..

We utilize the services of contract manufacturers to manufacture drug substance required for later phases of clinical development and commercialization for us under all applicable laws and regulations and are subject to long term forecasting obligations and certain minimum purchase requirements for all parts of the commercial supply chain.

We have analytical and process development capabilities in our own facility for R&D activities. We generally perform analytical and process development for our proprietary TransCon product candidates internally and manufacture internally our TransCon product candidates necessary to conduct the non-GLP preclinical studies thereof. However, we occasionally outsource the manufacture of research and development-stage TransCon product candidates.

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

Our contract suppliers manufacture drug substance and finished drug product for our TransCon products and product candidates for commercial and clinical trial use in effort to comply with current good manufacturing practice ("cGMP"), applicable local regulations and similar foreign requirements. cGMP and similar foreign requirements include requirements relating to organization of personnel; buildings and facilities; equipment; control of components and drug product containers and closures; production and process controls; packaging and labeling controls; holding and distribution; laboratory controls; records and reports; and returned or salvaged products. The manufacturing facilities for our products must be in compliance with cGMP requirements and similar foreign requirements, and for device and device components, the Quality Management System Regulation ("QMSR") requirements, before any product is approved. Our third-party manufacturers may also be subject to periodic inspections of facilities by the FDA, the EU member states competent authorities, 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.

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

NOF Manufacturing and Supply Agreement Related to TransCon PTH

On August 31, 2020, we entered into a multi-year Manufacturing and Supply Agreement (the "NOF PTH Agreement") with NOF. Under the NOF PTH Agreement, NOF has agreed to manufacture and supply the PEG maleimide (the "NOF PTH Product") for our TransCon PTH product candidate. We have agreed to purchase certain quantities of NOF PTH Product. We may purchase NOF PTH Product from other manufacturers and are not obligated to purchase NOF PTH Product from NOF, other than certain quantities that have been forecasted by us in accordance with a mandatory rolling forecast that we must deliver to NOF from time to time.

Carbogen Manufacturing and Supply Agreement Related to TransCon PTH

On May 27, 2021, we entered into a multi-year Manufacturing and Supply Agreement (the "Carbogen PTH Agreement") with Carbogen. Under the Carbogen PTH Agreement, Carbogen has agreed to manufacture and supply Linker F (the "Carbogen PTH Product") for our TransCon PTH product candidate. We may purchase Carbogen PTH Product from other manufacturers and are not obligated to purchase Carbogen PTH Product from Carbogen, other than certain quantities that have been forecasted by us in accordance with a mandatory rolling forecast that we must deliver to Carbogen from time to time.

Vetter Pharma International GmbH

On October 1, 2022, we entered into a multi-year Supply Agreement (as amended on April 8, 2024, the "PTH Vetter Agreement") with Vetter. Under the PTH Vetter Agreement, Vetter has agreed to manufacture and supply single chamber cartridges pre-filled with TransCon PTH (the "Ascendis PTH Product"). Vetter has agreed to supply in accordance with a long-term forecast and a rolling forecast with certain materials that we deliver to Vetter from time to time.

Bachem Manufacturing and Supply Agreement

On December 27, 2020, we entered into a multi-year Manufacturing and Supply Agreement (the "Bachem Agreement") with Bachem AG ("Bachem"). Under the Bachem Agreement, Bachem has agreed to manufacture and supply PTH drug substance (the "Bachem Product") for our TransCon PTH product candidate. We may purchase Bachem Product from other manufacturers and are not obligated to purchase Bachem Product from Bachem, other than certain quantities that have been forecasted by us in accordance with a mandatory rolling forecast that we must deliver to Bachem from time to time.

Competition

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

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

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

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

Intellectual Property

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

secrets that may be important to the development of our business and actively seek to protect the confidentiality of such trade secrets.

Our success will depend on our ability to obtain and maintain patents 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 valid and enforceable patents or otherwise misappropriate other intellectual property rights of third-parties. For more information, please see "Item 3 D. Key Information—Risk Factors—Risks Related to Our Intellectual Property."

As of December 31, 2025, we own over 465 granted patents and over 625 pending patent applications.

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

We own the following patents relating to our products and our pipeline (in addition to certain patents covering our early-stage product candidates):

For SKYTROFA and the related TransCon technology, we own twenty-one patents in the United States and Europe that will expire between 2026 and 2040. For the SKYTROFA Auto-Injector, we own twenty-six patents in the United States and Europe that will expire between 2036 and 2041.

For YORVIPATH and the related TransCon technology, we own fifteen patents in the United States and Europe that will expire between 2029 and 2042.

For TransCon CNP and the related TransCon technology, we own seventeen patents in the United States and Europe that will expire between 2027 and 2042.

We own 75 patents in the United States that we expect to expire between February 2026 and November 2042 and 33 patents in the European Union that we expect to expire between January 2029 and May 2039. In addition, we own more than 355 patents in jurisdictions outside of the United States and the European Union that expire between January 2029 and November 2042.

The information in the above list is based on our current assessment of patents that we own and is subject to revision, for example, in the event of changes in the law or legal rulings affecting our patents or if we become aware of new information. Significant legal issues remain unresolved as to the extent and scope of available patent protection for biotechnology products and processes in the U.S. and other important markets outside the U.S. We expect that litigation will likely be necessary to determine the term, validity, enforceability, and/or scope of certain of our patents and other proprietary rights. An adverse decision or ruling with respect to one or more of our patents could result in the loss of patent protection for a product and, in turn, the introduction of competitor products or follow-on biologics to the market earlier than anticipated, and could force us to either obtain third-party licenses at a material cost or cease using a technology or commercializing a product.

Laws and Regulations Regarding Patent Terms

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent term may be shortened if a patent is terminally disclaimed over another patent or if there are delays in patent prosecution by the patentee. A patent's term may be lengthened by a patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office 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. When our products received FDA approval in the past and if additional products receive FDA approval in the future, we have applied for and expect to apply upon future approvals for patent term extensions on patents covering those products. We anticipate that some of our granted patents may be eligible for patent term extensions.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, safety surveillance, efficacy, quality control, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, sale, import, export and the reporting of safety and other post-market information of pharmaceutical and medical device products such as those we are developing. Medicinal products, including drugs and biologics, must be approved or licensed by the FDA through the NDA or BLA process, before being able to be legally marketed in the US. 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 European Union ("EU") and in other 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, sponsors of drugs and biologics are subject to extensive regulation by the FDA, which regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and in the case of biologics, also under the Public Health Service Act ("PHSA") and their implementing regulations, and other federal, state, and local regulatory authorities. The FDCA, PHSA and their implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs or BLAs, withdrawal of an approval, imposition of a clinical hold on clinical studies, issuance of warning letters or other notices of violation, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

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

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice ("GLP") regulations, where applicable;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("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 ("GCP"), requirements to establish the safety and efficacy of the proposed drug or, or safety, purity and potency of the proposed biological product for each indication;
- submission to the FDA of an NDA or BLA;

- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with Current Good Manufacturing Practice ("cGMP") requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's or biologic's identity, strength, quality and purity;
- satisfactory completion of potential FDA inspection of selected clinical investigation sites to assess compliance with GCP; and
- FDA review and approval of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

Nonclinical Studies and Investigational New Drug Applications

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

Clinical Trials

Clinical trials involve the administration of the investigational pharmaceutical product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety (such as the required subject examinations, processes for tracking adverse events and required laboratory investigations), and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA. In addition, written safety reports regarding serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar pharmaceutical products, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure must be submitted to the FDA.

Furthermore, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Information about certain clinical trials must be submitted within specific timeframes to the NIH, for public dissemination on their www.clinicaltrials.gov website.

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

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, optimal dosage, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The product candidate is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific diseases and to determine optimal dosage.
- Phase 3: The product candidate is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, typically in well-controlled trials, to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

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

During the development of a new product candidate, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for FDA to provide advice, and for the sponsor and the FDA to reach consensus on the next phase of development.

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

Marketing Approval in the U.S.

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

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

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

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

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

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

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

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

Regulation of Combination Products in the United States

Certain products are comprised of components, such as drug components and device components, that would normally be subject to different regulatory frameworks by the FDA and frequently regulated by different centers at the FDA. These products are known as combination products. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. A combination product with a primary mode of action attributable to the drug component generally would be reviewed and approved pursuant to the drug approval processes set forth in the FDCA or PHSA by either the FDA's Center for Drug Evaluation and Research or the FDA's Center for Biologics Evaluation and Research, respectively. In reviewing the NDA or BLA for such a product, however, such FDA reviewers would consult with their counterparts in the FDA's Center for Devices and Radiological Health to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the QMSR applicable to medical devices.

Expedited Development and Review Programs

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

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

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

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

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

Post-Approval Requirements

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

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

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

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

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

Other potential consequences include, among other things:

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

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. A company can make only those claims relating to safety and efficacy, purity and potency that are in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgement, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Orphan Drug Designation

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

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

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

Biosimilars and Exclusivity

The Affordable Care Act ("ACA") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

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

Drug Product Exclusivity

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

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

Pediatric Exclusivity

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

Foreign Regulation

To market any product outside of the United States, sponsors need to comply with numerous and different 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. Foreign regulatory approval processes include all of the risks associated with FDA approval set forth above, as well as additional country and region-specific regulation.

Whether or not applicants obtain FDA approval for a product, companies must obtain approval of a product by the comparable regulatory authorities of foreign countries before commencing clinical trials or marketing of the product in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country, can involve additional testing or studies beyond that required by FDA, and may be longer or shorter than the FDA approval process. The requirements governing the conduct of clinical trials, product licensing, pricing, promotion, and reimbursement vary greatly from country to country.

Non-clinical Studies and Clinical Trials in the EU

Similar to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies (pharmaco-toxicological) must be conducted in compliance with the principles of GLP as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain medicinal products – e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines on GCP as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation ("EU CTR") repeals the EU Clinical Trials Directive, and became applicable on January 31, 2022. Unlike a Directive, the EU CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The EU CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via the Clinical Trials Information System ("CTIS"), which is a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate clinical trial application ("CTA"), to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the EU CTR introduced a centralized process and only requires the submission of a single application for multi-center trials. The EU CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. One of the main aims of EU CTR is to increase transparency about clinical trials, which is done by making documents and data from the CTA publicly available through CTIS at the time of decision about the clinical trial. There are few exceptions to this, and release of personal data and company confidential information may be controlled through redaction. The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with GMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization in the EU

In order to market our future product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization ("MA"). To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a MA application ("MAA"). The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- "Centralized MAs" are issued by the European Commission ("EC") through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use of the European Medicine Agency ("EMA"), and are valid throughout the EU. The centralized procedure is compulsory for certain types of medicinal products such as (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products) and (iv) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases or autoimmune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not authorized in the EU before May 20, 2004, or that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health in the EU. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops.
- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure.

Data and Marketing Exclusivity in the EU

In the EU, new products authorized for marketing (i.e., reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity upon MA. If granted, the data exclusivity period prevents generic and biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA 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. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

Orphan Medicinal Products in the EU

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States, albeit with some key differences in definition. A medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition (2) either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan designation must be requested before submitting an MAA. An EU orphan designation entitles a sponsor to incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to a ten years of market exclusivity for the approved indication, which means that the competent authorities cannot accept another MAA, or grant a MA, or accept an application to extend a MA for a similar medicinal product for the similar indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan ("PIP"). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan designation, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, MA may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

Pediatric Development in the EU

In the EU, MAAs for new medicinal products have to include the results of studies conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Paediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the product candidate for which MA 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 MA is obtained in all the EU member states and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two year extension of the orphan market exclusivity is granted.

Post-Approval Requirements in the EU

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance ("QPPV") who is responsible for the establishment and maintenance of that system and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All MAA must include a risk management plan ("RMP"), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The RMP must be updated any time new information on the medicinal product becomes available which has a significant impact on the content of the RMP. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and differ from one country to another.

The aforementioned EU rules are generally applicable in the European Economic Area ("EEA"), which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The EU pharmaceutical legislation has been undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products was published on April 26, 2023. The proposed changes were since discussed and negotiated by the European Parliament and the Council of the EU as part of the EU ordinary legislative process. A provisional agreement has been reached by the European Parliament and Council of the EU on the proposed revisions on December 11, 2025. The proposed revisions (affecting the duration of regulatory data protection and market protection, including for orphan medicinal products, revising the eligibility for expedited pathways, etc.) remain to be formally adopted by the two institutions, which is not anticipated before early 2026. The proposed changes are not expected to enter into application before 2028.

Brexit and the Regulatory Framework in the United Kingdom

Since January 1, 2021, the Medicines and Healthcare products Regulatory Agency ("MHRA") is the UK's standalone medicines and medical devices regulator. On January 1, 2025, an arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland (which had previously remained subject to EU rules) under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labelling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the now-repealed EU Clinical Trials Directive. On April 28, 2025, the UK adopted an amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 intended to support a more streamlined and flexible regulation of clinical trials, removing unnecessary administrative burdens on trial sponsors, while protecting the interests of trial participants. It also intends to bring the UK regulatory framework for clinical trials, which is still based on the EU Clinical Trials Directive, into closer alignment with the EU CTR. The amendment will become applicable on April 28, 2026 following a one-year transition period.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. In order to use the centralized procedure to obtain an MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore after Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized MAs. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to commercialize products in the UK. In addition, an international recognition procedure has been in place since

January 1, 2024, which allows the MHRA to take into account the expertise and decision-making of trusted partner agencies, such as the European Medicines Agency, when determining an application for a new UK MA.

There is no pre-MA orphan designation in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MA application. The criteria are essentially the same, but have been tailored for the market, i.e., the prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. Should an orphan designation be granted, the period or market exclusivity will be set from the date of first approval of the product in the UK.

Regulation of Combination Products in the EU

The EU regulates medical devices and medicinal products separately, through different legislative instruments, and the applicable requirements will vary depending on the type of drug-device combination product. Guidances have been published to help manufacturers select the right regulatory framework.

Drug-delivery products intended to administer a medicinal product where the medicinal product and the device form a single integral product are regulated as medicinal products in the EU. The EMA is responsible for evaluating the quality, safety and efficacy of MAAs submitted through the centralized procedure, including the safety and performance of the medical device in relation to its use with the medicinal product. The EMA or the EU member state national competent authority will assess the product in accordance with the rules for medicinal products described above but the device part must comply with the Medical Devices Regulation (including the general safety and performance requirements provided in Annex I). MAA must include—where available—the results of the assessment of the conformity of the device part with the Medical Devices Regulation contained in the manufacturer's EU declaration of conformity of the device or the relevant certificate issued by a notified body. If the MAA does not include the results of the conformity assessment and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required, the competent authority must require the applicant to provide a notified body opinion on the conformity of the device.

By contrast, in case of drug-delivery products intended to administer a medicinal product where the device and the medicinal product do not form a single integral product (but are, e.g., co-packaged), the medicinal product is regulated in accordance with the rules for medicinal products described above while the device part is regulated as a medical device and will have to comply with all the requirements set forth by the EU Medical Devices Regulation ("EU MDR").

The characteristics of non-integral devices used for the administration of medicinal products may impact the quality, safety and efficacy profile of the medicinal products. To the extent that administration devices are co-packaged with the medicinal product or, in exceptional cases, where the use of a specific type of administration device is specifically provided for in the product information of the medicinal product, additional information may need to be provided in the MAA for the medicinal product on the characteristics of the medical device(s) that may impact on the quality, safety and/or efficacy of the medicinal product.

The requirements regarding quality documentation for medicinal products when used with a medical device, including single integral products, co-packaged and referenced products, are outlined in the EMA guideline of July 22, 2021, which became applicable as of January 1, 2022.

The aforementioned EU rules are generally applicable in the EEA.

Rest of the World Regulation

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America, Asia, or Japan, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Healthcare Laws

In addition to FDA restrictions on marketing of `pharmaceutical products, other U.S. federal, state and foreign healthcare regulatory laws, regulations and industry codes restrict business practices in the biopharmaceutical industry, which include, but are not limited to, state, federal and foreign anti-kickback, false claims, and transparency laws regarding drug pricing and payments or other items of value provided to physicians and other healthcare providers.

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

The federal civil False Claims Act prohibits any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-covered, uses. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

In addition, the civil monetary penalties statute imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

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

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Physician Payments Sunshine Act imposed, among other things, annual reporting requirements for covered manufacturers for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Covered manufacturers must submit reports by the 90th day of each subsequent calendar year.

The majority of states also have anti-kickback and other fraud and abuse laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers. Certain states also require implementation of compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices, and/or tracking and reporting of marketing expenditures and pricing information as well as gifts, compensation and other remuneration or items of value provided to physicians and other healthcare professionals and entities.

Moreover, analogous state and foreign laws, regulations and industry codes may be broader in scope than the provisions described above and may apply regardless of payor. These laws and regulations may differ from one another in significant ways, thus further complicating compliance efforts. For instance, in the EU, many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medicinal products, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted regional and national "Sunshine Acts" which impose reporting and transparency requirements, similar to the requirements in the United States, on pharmaceutical companies. Certain countries also mandate implementation of commercial compliance programs, or require disclosure of marketing expenditures and pricing information.

Violation of any of such laws, regulations and industry codes or any other governmental regulations that apply to drug manufacturers may result in significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment.

Coverage and Reimbursement

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

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

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drugs, medical devices and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. In addition, in many foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. In the EU, governments influence the price of products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. Member states may approve a specific price or level of reimbursement for the pharmaceutical product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the pharmaceutical product on the market, including volume-based arrangements, caps and reference pricing mechanisms. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. The downward pressure on healthcare costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from lower priced markets exert a commercial pressure on pricing within a country.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in 2010, the ACA was enacted, which, among other things, (i) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, (ii) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, (iii) extended rebate liability under the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans, and (iv) subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include the Budget Control Act of 2011, which resulted in reductions in Medicare payments to providers, which went into effect on April 1, 2013 and will stay in effect through 2032, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced certain Medicare payments to several types of providers, including hospitals. The legislation also increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

Significantly, the Inflation Reduction Act ("IRA") was signed into law in 2022. The IRA marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discount program (beginning in 2025). The Centers for Medicare & Medicaid Services has published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and the subsequent 15 drugs, which will first be effective in 2027. The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined but is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of SKYTROFA®, YORVIPATH® or any product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how these proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for SKYTROFA®, YORVIPATH®, and any other product candidates that we commercialize. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the current administration is pursuing traditional regulatory pathways to impose drug pricing policies and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the U.S. that is based on drug prices outside the U.S. would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

At the state level, state governments have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for any of our current and future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

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

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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

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

In 2011, Directive 2011/24/EU was adopted at the EU level. This Directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement. While the Regulation entered into force in January 2022, it entered into application on January 12, 2025, with preparatory and implementation-related steps taking place in the interim. The Regulation has a phased implementation depending on the concerned products. As a first step, these new rules started applying to MAAs for new oncology and advanced therapy medicinal products as of January 12, 2025. The rules will be extended to orphan medicinal products in January 2028 and will as of 2030 cover all new medicinal products.

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

Data Privacy and Security

Privacy, use of AI and data security have become significant concerns around the world including United States, Europe and in many other jurisdictions where we may in the future conduct our operations. As we receive and, process personal and confidential data, we become subject to numerous laws and regulations relating to data privacy, AI and security, such as data breach notification laws, health information laws, AI regulations and consumer protection laws in the United States and abroad including the GDPR and the U.K. GDPR. These laws and regulations are complex and constantly evolving, and any unauthorized access, use, disclosure and other loss of personal data, including by third party vendors providing support services, can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties, restrictions on data processing and reputational damage.

C. Organizational Structure

Certain of our operations are conducted through our wholly-owned subsidiaries. These subsidiaries are set forth in Exhibit 8.1 to this annual report.

D. Property, Plants and Equipment

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

Our corporate headquarters is located in Hellerup, Denmark. In addition, we have offices and research and development facilities in Germany and the United States. Further, we are expanding our commercial infrastructure in the U.S. and Europe, where we have sales and representative offices in Germany, France, Spain, Italy, Switzerland, Portugal and the United Kingdom. Since we do not own facilities for manufacturing of our products and product candidates, we engage with Contract Manufacturing Organizations (“CMOs”) to manufacture commercial and clinical trial supply.

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

Location	Size (in square meters)	Primary usage	Enforceable lease period	Option to extend the lease beyond enforceable lease period
Denmark				
Tuborg Boulevard, Hellerup	17,262	Corporate headquarters, Administration and R&D	July, 2029 - May, 2038	No
Germany				
Grüne Meile, Heidelberg	11,762	Administration, R&D and laboratory facilities	October, 2040	Option to extend for additional five years
United States				
Palo Alto, California[1]	6,765	Administration	October, 2033	Option to extend for up to two periods of five years each
Redwood City, California[2]	3,681	R&D and laboratory facilities	April, 2030	Option to extend for additional five years
West Windsor Township, New Jersey	2,048	Selling and administration	February, 2031	Option to extend for additional five years

(1) 50% of our lease in Palo Alto, California is subleased, with commencement date of January 1, 2026.

(2) Our lease in Redwood City, California is subleased to Eyconis. See "Item 7 B. Major Shareholders and Related Party Transactions—Related Party Transactions" for more information about Eyconis.

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

Item 4A Unresolved Staff Comments

Not applicable.

Item 5 Operating and Financial Review and Prospects

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and related notes appearing elsewhere in this annual report. In addition to historical information, this discussion contains forward-looking statements based on our current expectations that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the "Item 3 D. Key Information—Risk Factors" and "Special Note Regarding Forward-Looking Statements" sections and elsewhere in this annual report.

A. Operating Results

Refer to Part I, Item 5 in our Annual Report on Form 20-F for the financial year ended December 31, 2024 (filed with the SEC on February 12, 2025) for additional discussion of our financial condition and results of operations for the year ended December 31, 2023, as well as our financial condition and results of operations for the year ended December 31, 2024, compared to the year ended December 31, 2023.

Overview

For a description of business highlights in 2025, please refer to "Item 4B. Information on the Company—Business Overview."

Financial Operations Overview

Income and Expenses

Revenue from sale of commercial products and clinical trial supply is recognized when the customer has obtained control of the goods and it is probable that we will collect the consideration to which we are entitled for transferring the goods. Control is transferred upon delivery. Cost of sales are recognized when the sales take place. Rendering of services is recognized as revenue over the service period as stipulated under the applicable agreement. License agreements which transfer rights to our intellectual property ("IP") with significant stand-alone value are classified as "right-to-use," with revenue recognized at the point in time when the customer can use and benefit from the IP.

Our operating expenses relate to research and development activities and to selling, general, and administration activities. Research and development expenses ("R&D expenses") consist primarily of product development and pre-commercial manufacturing costs, preclinical and clinical study costs and costs for process optimizations and improvements performed by Clinical Research Organizations ("CROs") and Contract Manufacturing Organizations ("CMOs"), salaries and other personnel costs including pension and share-based payment, the cost of facilities, professional fees, cost of obtaining and maintaining our IP portfolio, and depreciation of non-current assets used in research and development activities. Selling, general, and administrative expenses ("SG&A expenses") comprise salaries and other personnel costs including pension and share-based payment, office supplies, cost of facilities, professional fees, and depreciation and amortization of non-current assets related to selling, general, and administrative activities, and pre-commercial and commercial activities.

A material portion of our operating expenses are denominated in other currencies than the Euro, which expose our operating expenses to volatility. We do not currently enter into derivative financial instruments to manage our exposure to foreign exchange risks.

Operating Assets and Liabilities

Our operating assets and liabilities primarily relate to property, plant and equipment, inventories, receivables, prepayments and accruals for development costs, lease liabilities, trade payables, other liabilities, and contract liabilities. Property, plant and equipment primarily relate to leased facilities which are recognized and measured as right-of-use assets. Our receivables and liabilities are exposed to development in foreign currencies, primarily with respect to the U.S. Dollar. Please refer to the "Foreign Currency Risk" section under "Item 11 Quantitative and Qualitative Disclosures about Market Risk" and to Note 18, "Financial Risk Management," for an analysis of our foreign currency exposure.

We have built up inventories to support the commercialization of YORVIPATH® and SKYTROFA®. In addition to commercial inventories, manufacturing of pre-launch inventories is initiated for late-stage product candidates and is recognized as inventories. However, since pre-launch inventories are not realizable prior to obtaining marketing approvals, pre-launch inventories are immediately written down to zero through research and development expenses.

Capital Structure

Our capital structure consists of equity and external borrowings obtained through issuance of convertible senior notes ("convertible notes") and royalty funding liabilities. We are not subject to any contractually imposed capital requirements or financial covenants. For further details, please refer to "Item 5 B. Operating and Financial Review and Prospects—Liquidity and Capital Resources" and Note 17, "Financial Assets and Liabilities" for further information about our convertible notes and royalty funding agreements.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

Financial Highlights

(EUR'000)	2025	2024	Change
Revenue	720,132	363,641	356,491
Gross profit	625,217	319,383	305,834
Operating expenses [(1)]	(761,488)	(598,146)	(163,342)
Operating profit/(loss)	(136,271)	(278,763)	142,492
Net profit/(loss) for the year	(228,034)	(378,084)	150,050
Cash flows from/(used in) operating activities	53,897	(306,197)	360,094

(1) Operating expenses comprise research and development expenses and selling, general and administrative expenses.

Compared to the year ended December 31, 2024, revenue for the year ended December 31, 2025, primarily benefited from the continued growth of YORVIPATH global sales. Operating loss was €136.3 million, representing an improvement of €142.5 million compared to December 31, 2024, which, in addition to an increase in revenue, was impacted by higher operating expenses related to commercial expansion. We had a net loss of €228.0 million for the year ended December 31, 2025, which, in addition to operating loss, was driven primarily by non-cash financial items. In addition, net loss was positively impacted by share of profit/(loss) of associates, which includes a non-cash gain of €35.7 million related to the Initial Public Offering of VISEN in March 2025.

Cash flows from operating activities were positive for the year ended December 31, 2025 representing an improvement of €360.1 million, compared to last year, attributable to improved operating performance. Refer to section "Liquidity and Capital Resources" for further information.

Foreign currency translation reduced reported revenue for the year ended December 31, 2025 by €38.9 million compared to last year's exchange rate. Similarly, operating expenses decreased due to currency translation by €14.6 million compared to last year.

Our total equity presented a deficit of €162.8 million as of December 31, 2025, compared to a deficit of €105.7 million as of December 31, 2024.

Further details about our results of operations are described in the following sections.

Revenue

The following table summarizes our revenue for the years ended December 31, 2025 and 2024:

(EUR'000)	2025	2024	Change
Commercial products	683,572	225,728	457,844
Services and clinical supply	18,008	15,570	2,438
Licenses	5,630	122,343	(116,713)
Milestones	12,922	—	12,922
Total revenue	**720,132**	**363,641**	**356,491**

Revenue for the year ended December 31, 2025 was €720.1 million, representing an increase of €356.5 million compared to last year. This increase was primarily attributable to the continued growth of YORVIPATH global sales, partly offset by the recognition of a $100 million upfront payment in 2024 related to our exclusive license agreement with Novo Nordisk.

Revenue from sale of commercial products was as follows:

(EUR'000)	2025	2024	Change
Revenue from commercial products			
YORVIPATH®	477,412	28,727	448,685
SKYTROFA®	206,160	197,001	9,159
Total revenue from commercial products	**683,572**	**225,728**	**457,844**

Cost of Sales

Cost of sales for the year ended December 31, 2025 was €94.9 million, representing an increase of €50.7 million compared to last year. This increase was primarily attributable to increased sales of commercial products and costs under our Strategic Collaborations.

Research and Development Expenses

The following table specifies external project costs on the development pipeline and other R&D expenses.

(EUR'000)	2025	2024	Change
External project costs			
Hypoparathyroidism	11,979	6,777	5,202
Growth Disorders	84,367	102,385	(18,018)
Oncology	33,791	41,166	(7,375)
Other project costs	2,112	1,656	456
Total external project costs	**132,249**	**151,984**	**(19,735)**
Other research and development expenses			
Employee costs	145,673	131,867	13,806
Other external costs	14,378	15,698	(1,320)
Depreciation, amortization and impairment	11,321	7,455	3,866
Total other research and development expenses	**171,372**	**155,020**	**16,352**
Total research and development expenses	**303,621**	**307,004**	**(3,383)**

R&D expenses for the year ended December 31, 2025 were €303.6 million representing a decrease of €3.4 million compared to last year. This decrease was primarily due to completion of certain clinical trials and development activities within our Endocrinology Rare Disease pipeline, partly offset by reversal (income) of prior period write-downs related to pre-launch inventories for Hypoparathyroidism in 2024 of €12.6 million due to the launch of YORVIPATH, and by higher employee costs to support future growth.

Selling, General, and Administrative Expenses

The following table specifies SG&A expenses:

(EUR'000)	2025	2024	Change
Selling, general, and administrative expenses			
Employee costs	210,418	144,181	66,237
External costs	237,626	139,899	97,727
Depreciation, amortization and impairment	9,823	7,062	2,761
Total selling, general, and administrative expenses	**457,867**	**291,142**	**166,725**

SG&A expenses for the year ended December 31, 2025 were €457.9 million representing an increase of €166.7 million compared to last year. This increase was primarily due to the continued impact from global commercial expansion, including global launch activities for YORVIPATH.

Finance Income and Finance Expenses

The following table specifies the result of finance income and expenses, further disaggregated into cash and non-cash items:

(EUR'000)	2025	2024	Change
Net finance income/(expenses)			
Finance income	113,999	25,609	88,390
Finance expenses	(206,687)	(100,027)	(106,660)
Total net finance income/(expenses)	**(92,688)**	**(74,418)**	**(18,270)**
Specified in cash and non-cash items			
Cash items			
Finance income received	15,302	14,374	928
Finance expenses paid	(22,935)	(15,205)	(7,730)
Non-cash items			
Remeasurement gain/(loss) of financial liabilities	(105,571)	3,874	(109,445)
Currency gain/(loss)	78,229	(27,149)	105,378
Amortization charges, accruals, and other items	(57,713)	(50,312)	(7,401)
Total net finance income/(expenses)	**(92,688)**	**(74,418)**	**(18,270)**
Interest expenses measured under the effective interest method, related to:			
Convertible senior notes	(36,675)	(36,116)	(559)
Royalty funding liabilities	(39,572)	(26,000)	(13,572)
Lease liabilities	(4,186)	(3,303)	(883)

The development in non-cash items was driven primarily by remeasurement loss from financial liabilities, partly offset by translation net-gain of U.S. dollar denominated monetary positions into Euro, primarily cash and cash equivalents, convertible notes and royalty funding liabilities. The development was further driven by amortization charges, accruals, and other items, primarily due to our royalty funding liabilities which we entered into in September 2023 and September 2024.

B. Liquidity and Capital Resources

Our liquidity and capital resources comprise cash and cash equivalents. As of December 31, 2025, these amounted to €616.0 million.

Our expenditures primarily relate to research and development activities and selling, general, and administrative activities to support our business, including our continued development of products and product candidates within Endocrinology Rare Disease and Oncology portfolios, the commercialization of YORVIPATH and SKYTROFA, and expenses made in anticipation of potential future product launches. We manage our liquidity risk by maintaining adequate cash reserves. The risk of shortage of funds is monitored, through the financial forecasting process, to ensure sufficient funds are available to settle liabilities as they fall due.

As of December 31, 2025, the equity in the consolidated statements of financial position presented a deficit of €162.8 million. Under Danish corporate law, as Ascendis Pharma A/S, the parent company of the Company, holds a positive balance of equity, the Company is currently not subject to legal or regulatory requirements to re-establish the balance of equity. There is no direct impact from the negative balance of equity to the liquidity and capital resources.

Historically, we have funded our operations primarily through the issuance of preference shares, ordinary shares (including public offerings and exercise of warrants), convertible debt securities, payments to us made under collaboration agreements, and our royalty funding agreements. Including our initial public offering, since February 2015, we have completed public offerings of American Depositary Shares ("ADSs"), latest in September 2024, with total net proceeds of $2,580.2 million (or €2,259.0 million at the time of the offerings). Refer to Note 17, "Financial Assets and Liabilities" for further information about our convertible notes and royalty funding agreements.

Cash requirements

We maintain cash-forecasts to ensure sufficient cash reserves are available to settle liabilities as they come due.

As of December 31, 2025, our cash requirements primarily relate to the following:

- Semi-annual interest payments and potential repayment (April 1, 2028) of principal amount of convertible notes;
- Payments to Royalty Pharma under our royalty funding agreements of 3% on net revenue from sales of YORVIPATH in the U.S., and 9.15% on net revenue from sales of SKYTROFA in the U.S., subject to caps as described in Note 17, "Financial Assets and Liabilities;"
- Lease obligations related to our office, research and development facilities;
- Purchase obligations under our commercial supply agreements and related activities;
- Research and development activities related to clinical trials for our product candidates in clinical development;
- Operating an integrated organization to support the ongoing commercialization of YORVIPATH and SKYTROFA in the U.S. and Europe; and
- Purchase of the Company's own ADSs in connection with settlements of equity incentive plans.

Our cash requirements are determined in Euro applying foreign exchange rates at December 31, 2025. Accordingly, actual cash payments are exposed to development in foreign currencies, primarily with respect to the U.S. Dollar. For a description of our exposure to market risks, credit risk and liquidity risk, refer to Note 18, "Financial Risk Management."

Our borrowings comprise convertible notes, royalty funding liabilities and lease liabilities. As of December 31, 2025, short-term (payable within twelve months after the reporting date) and long-term (payable beyond twelve months after the reporting date) expected cash requirements (on an undiscounted basis) for convertible notes and royalty funding liabilities were €51.1 million and €952.8 million, respectively. Expected maturity for royalty

funding liabilities is based on anticipated amount and timing of future revenue from sale of commercial products. Further details regarding the payment structure of the royalty funding agreements and convertible notes are provided in Note 17, "Financial Assets and Liabilities."

As of December 31, 2025, the length of non-cancellable leases is up to 15 years. Our cash requirements for lease obligations (on an undiscounted basis) are €20.4 million and €176.2 million, for short-term and long-term, respectively. In addition, our lease obligations establish ancillary contractual commitments in relation to utilities, maintenance, levies, and other services. Further, we have commitments related to short-term leases and leases of low value assets, IT and facility related services. Costs relating to those commitments are expensed as incurred.

We have also entered into long-term commercial supply agreements, primarily related to commercial manufacturing of YORVIPATH and SKYTROFA. Commercial supply agreements may include purchase obligations, usually determined on binding and non-binding supply forecasts, that are subject to continuous negotiation and adjustments according to individual contractual terms and conditions. As of December 31, 2025, our short-term and long-term cash requirements were €46.3 million and €120.3 million, respectively, excluding non-binding commitments for purchase of raw materials and intermediates used in the manufacturing process.

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

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

Based on our current operating plan, we currently estimate that our existing cash and cash equivalents will be sufficient to fund our operations for at least twelve months from the date of this annual report. However, our operating plan and actual cash requirements may change as a result of many factors. For example our future funding requirements will depend on many factors, including, but not limited to those described in "Item 3.D – Key Information—Risk Factors—Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements" in this annual report.

Additional funds may not be available if we need them or 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 and commercialization activities.

The following table summarizes our cash flows for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		
(EUR'000)	**2025**	**2024**	**Change**
Cash flows from / (used in)			
Operating activities	53,897	(306,197)	360,094
Investing activities	(8,485)	6,876	(15,361)
Financing activities	36,328	443,929	(407,601)
Increase/(decrease) in cash and cash equivalents	**81,740**	**144,608**	**(62,868)**

Cash flows from/(used in) Operating Activities

Cash flows from operating activities for the year ended December 31, 2025 were €53.9 million, representing an improvement of €360.1 million compared to last year, of which €182.0 million related to improved operating performance, primarily driven by commercial revenue growth, and €178.1 million related to working capital improvements, which include settlement of the upfront payment from our exclusive license agreement with Novo Nordisk of $100 million plus related indirect taxes.

Cash flows from/(used in) Investing Activities

Cash flows used in investing activities for the year ended December 31, 2025 were €8.5 million, representing an increase of €15.4 million compared to last year. This increase was primarily attributable to €7.3 million settlements of marketable securities in 2024 and from leasehold improvements in 2025.

Cash Flows from/(used in) Financing Activities

Cash flows from financing activities for the year ended December 31, 2025, were €36.3 million, representing a decrease of €407.6 million compared to the last year. This decrease was primarily due to:

- The follow-on public offering of ADSs with net proceeds of €290.6 million and the $150.0 million capped synthetic royalty funding agreement with Royalty Pharma, with net proceeds of €134.2 million, both completed in September 2024;
- Acquisition of treasury shares of €17.4 million in 2025; and
- Payment of withholding taxes under stock incentive programs of €11.4 million in 2025, partly offset by increased warrant exercise activity of €56.6 million in 2025.

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

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

D. Trend Information

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

E. Critical Accounting Estimates

The consolidated financial statements are prepared in accordance with the IFRS Accounting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"), and as adopted by the European Union ("EU"). A description of critical accounting estimates is provided in Note 3, "Significant Accounting Judgements and Estimates" under the Significant Estimation Uncertainties sub-section in the audited consolidated financial statements as of and for the years ended December 31, 2025, 2024 and 2023, of this annual report.

Item 6 Directors, Senior Management and Employees

A. Directors and Senior Management

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

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

Board of Directors

The following table sets forth information with respect to each of our current board members as of the date of this annual report. All members of our board of directors are elected for one year and eligible for re-election at each annual general meeting. Our board of directors currently consists of six members.

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

Name of Board Member	Age	Position(s)
Albert Cha, M.D., Ph.D.	53	Chairman and Board Member
Lisa Bright	58	Board Member
William Carl Fairey Jr.	61	Board Member
Lars Holtug, M.Sc.	67	Board Member
Siham Imani	48	Board Member
Jan Møller Mikkelsen	66	President, Chief Executive Officer and Board Member

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

Albert Cha, M.D., Ph.D. has served as a member of our board of directors since November 2014 and as the Chairman of our board of directors since May 2021. Dr. Cha is a Managing Partner with Frazier Life Sciences. He previously was a managing partner at Vivo Capital LLC, a healthcare investment firm, where he has served in various positions, most recently as a managing partner. Dr. Cha previously served as a member of the board of directors of KalVista Pharmaceuticals, Inc., Aclaris Therapeutics, a publicly traded dermatology company, Sierra Oncology, Inc., a publicly traded oncology company, Biohaven Pharmaceutical Holding Company Ltd, a publicly traded clinical-stage biopharmaceutical company targeting neurological diseases and Menlo Therapeutics, Inc., a publicly traded late-stage biopharmaceutical company focused on the treatment of pruritus. Dr. Cha holds a B.S. and an M.S. from Stanford University and an M.D. and a Ph.D. from the University of California at Los Angeles.

Lisa Bright has served as a member of our board of directors since April 2017. Ms. Bright has over 30 years of executive experience in global life sciences companies and over five years' experience serving as a member of the board of directors of a number of public and private companies. Ms. Bright is currently on the board of Immedica Pharma AB, a pharmaceutical company, and serves as Chair of the board of Metadeq Inc, a medical diagnostics company and DRI Capital, a private equity fund. She previously served as the Chair of the board of Resolution Therapeutics Ltd, a biotechnology company, and as a Non-Executive Director of Dechra Pharmaceuticals PLC, a veterinary pharmaceutical company. She is also an Executive Partner to Syncona Limited, an investment trust dedicated to life science investments. Previously, she served as President International for Intercept Pharmaceuticals, Inc., a biopharmaceutical company, from July 2016 to January 2021, and from November 2014 to July 2016 as Chief Commercial and Corporate Affairs Officer and Senior Vice President, Head of EUCA. During her tenure at Intercept, Ms. Bright oversaw the development of the global launch of an orphan medicine in the United States and Europe, including building the commercial organization in the United States and establishing legal affiliates and teams across Europe and Canada. From 2008 to November 2014, Ms. Bright held various leadership positions at Gilead Sciences Ltd., a biopharmaceutical company, including Vice President, Head of Government Affairs, Europe, Asia, Middle East and Australasia, Vice President and Head of HCV Launch Planning, Vice President and Head of Northern Europe and General Manager, UK and Ireland. Prior to Gilead Sciences, Ms. Bright served in various positions of increasing responsibility at GlaxoSmithKline plc from 1997 to 2006 including Vice President Commercial Planning and Operations and Vice President General Manager NZ and Vice President Head of Sales, UK and Ireland. Prior to that, Ms. Bright also worked at Sanofi from 1992 to 1996 and GlaxoSmithKline from 1989 to 1992. Ms. Bright received her B.Sc. in Pharmacology from University College London, United Kingdom.

William Carl Fairey Jr. has served as a member of our board of directors since September 2022. Mr. Fairey currently serves as Executive Chairman of Respira Therapeutics, Inc., a clinical-stage company developing inhaled therapeutics for cardiopulmonary diseases, a position he has held since January 2022. Since August 2021, Mr. Fairey has also served as a director of Mirum Pharmaceuticals, a publicly-traded biotechnology company developing therapies for rare liver diseases; since November 2023, he has served on the board of REIN Therapeutics, a public clinical-stage biopharmaceutical company; and since June 2024, he has served on the board of KalVista, a publicly-traded pharmaceutical company developing therapies for hereditary angioedema. Prior to Respira, Mr. Fairey was Executive Vice President and Chief Commercial Officer of MyoKardia, Inc., a publicly-traded clinical-stage biopharmaceutical company, from January 2019 until November 2020 when the company was acquired by Bristol-Myers Squibb. From January 2018 until January 2019, Mr. Fairey served as Executive Vice President and Chief Operating Officer of ChemoCentryx, Inc., a publicly-traded biopharmaceutical company developing therapeutics to treat autoimmune diseases, inflammatory disorders and cancer, primarily focused on orphan and rare diseases. Before ChemoCentryx, between 2001 and 2017, Mr. Fairey served in various positions of increasing responsibility at Actelion Pharmaceuticals, including as President of Actelion's U.S. division, as well as Vice President, Asia Pacific Region, Managing Director and Vice President, Australia Asia Pacific Region, President of Actelion Canada, and Vice President, US Sales and Managed Markets. Mr. Fairey began his pharmaceutical career as Business Director, Healthcare Management for the Parke-Davis Division of Warner-Lambert between 1988 and 2000. Mr. Fairey received a B.S. in Biology from the University of Oregon and an M.B.A. from Saint Mary's College of California.

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

Siham Imani has served as a member of our board of directors since September 2022. Ms. Imani currently serves as Executive Vice President of Strategy, Sustainability and Growth at Chiesi Farmaceutici S.p.A., a pharmaceutical company. Before joining Chiesi, Ms. Imani was EVP Corporate Strategy & Business Development at Servier, where she contributed to the Group transformation as a leader in Cardio Metabolism and Oncology. Prior to Servier, Ms. Imani held various positions of increasing responsibility at Ipsen, a French pharmaceutical company specializing in oncology, neuroscience and rare diseases, including Vice President European Business Unit Pediatric Endocrinology, Vice President Commercial Transformation & Support, Vice President Corporate Strategic Planning and Executive Committee Secretary, from 2011 until April 2017. Ms. Imani also worked for Pierre Fabre and Biosense Webster, part of the Johnson & Johnson Family of Companies, from 2005 to 2010. Ms. Imani is also a board member at Lapropan, a pharmaceutical company. Ms. Imani received a Master in Economics and a Master in Chemistry from École Polytechnique in Palaiseau, France and an M.B.A. from Stanford University.

Executive Board and Senior Management

The following table sets forth information with respect to each of the members of our senior management as of the date of this annual report. In addition to serving as members of our senior management, Mr. Mikkelsen, Mr. Smith, Mr. Wolff Jensen, and Ms. Sønderbjerg serve as the members of our executive board. The business address of these individuals is our registered office address at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark.

Name	Age	Position(s)
Jan Møller Mikkelsen	66	President, Chief Executive Officer and Board Member
Jethro Ekuta, D.V.M., Ph.D.	62	Chief Regulatory & Safety Officer
Sherrie Glass, MPA	54	Chief Business Officer
Flemming Steen Jensen	64	Executive Vice President, Product Supply and Quality
Michael Wolff Jensen, L.L.M.	54	Executive Vice President, Chief Legal Officer
Stina Singel, M.D., Ph.D.	52	Executive Vice President, Head of Clinical Development, Oncology
Scott T. Smith	52	Executive Vice President, Chief Financial Officer
Lotte Sønderbjerg	64	Executive Vice President, Chief Administrative Officer
Kennett Sprogøe, Ph.D.	47	Executive Vice President, Head of Innovation and Research
Aimee Shu, M.D.	49	Executive Vice President, Chief Medical Officer
Jay Donovan Wu	40	Executive Vice President, U.S. President
Mads Bodenhoff	57	Senior Vice President, Head of 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 founded Ascendis Pharma and has served as President and Chief Executive Officer as well as a Board member since December 2007. From 2002 to 2006, Mr. Mikkelsen served as President and Chief Executive Officer of LifeCycle Pharma A/S, now Veloxis Pharmaceuticals A/S, which was a publicly traded biotechnology company. From 2000 to 2002, Mr. Mikkelsen was President of the Pharmaceutical Division of Maxygen, Inc. Prior to that, Mr. Mikkelsen co-founded ProFound Pharma A/S, a biopharmaceutical company that was later acquired by Maxygen, Inc., and at ProFound, he served as Co-Chief Executive Officer from 1999 to 2000. From 1988 to 1999, Mr. Mikkelsen held various positions at Novo Nordisk A/S, a global healthcare company, including Vice President of Protein Discovery. Mr. Mikkelsen currently serves as a member of the advisory board of Inspirion Delivery Technologies, a specialty pharmaceutical company. Mr. Mikkelsen received a Cand. Scient. degree in Biochemistry from the University of Odense, Denmark, and pursued his post-doctoral research at Children's Hospital in Oakland, CA.

Jethro Ekuta, D.V.M., Ph.D. has served as Chief Regulatory & Safety Officer at Ascendis Pharma since November 2024, where he heads Global Regulatory Affairs & Pharmacovigilance. Prior to joining Ascendis, Dr. Ekuta was Vice President, Head of Regulatory Science Delivery at Alexion, AstraZeneca Rare Disease from 2019 to 2024, where he built Global Labeling, Established Products, and Advertising and Compliance Teams; served as US Regulatory Lead; and led various initiatives related to process improvement, talent development, and integrations and acquisitions. From 2018 to 2019, he served as Senior Vice President, Global Head of Regulatory, Safety and Standards at Horizon Therapeutics. Before Horizon, he held Regulatory and Pharmacovigilance roles of increasing responsibility at companies that included Johnson & Johnson, Genzyme-Sanofi, Bristol-Myers Squibb, Pfizer, and Procter & Gamble Pharmaceuticals. Prior to joining industry, Dr. Ekuta was a Staff Fellow in Clinical Pharmacology at the Center for Drug Evaluation and Research (CDER), US Food and Drug Administration (FDA). He completed his U.S. National Institutes of Health (NIH)-sponsored post-doctoral fellowship training in neuropharmacology and cardiovascular pharmacology at Meharry Medical College, and an FDA-sponsored post-doctoral fellowship in clinical pharmacology at Vanderbilt University Medical Center. Dr. Ekuta holds a Doctor of Veterinary Medicine (D.V.M.) degree from Ahmadu Bello University, a Ph.D. in Pharmacology & Toxicology from the University of Mississippi, and an Executive MBA from Quantic School of Business and Technology. He is certified in Regulatory Affairs (RAC) and is an inaugural Fellow of the Regulatory Affairs Professionals Society (FRAPS). Dr. Ekuta has served as President, RAPS Board of Directors from 2023 to 2024 and currently serves as Chair of the Board.

Sherrie Glass, MPA has served as Chief Business Officer at Ascendis Pharma since September 2024. Prior to joining Ascendis, Ms. Glass was Senior Vice President, Enterprise Strategy, Strategy and Business Development at Bristol Myers Squibb from May 2021 to March 2024.From January 2019 to May 2021, Ms. Glass served as Vice President, Managed Markets Pipeline Access and Strategy at Allergan (acquired by AbbVie in May 2020). From November 2015 to December 2018, Ms. Glass served as Vice President, Strategy and Corporate Initiatives at Allergan. Prior to Allergan, Ms. Glass was a Principal at The Boston Consulting Group from 2011 to 2015. Ms. Glass received her Master of Public Administration from Princeton University and Bachelor of Arts in History and Religious Studies from Brown University.

Flemming Steen Jensen has served as our Executive Vice President, Product Supply and Quality since January 2023 and previously served as our Senior Vice President, Product Supply and Quality from August 2015 until January 2023. Prior to this, Mr. Jensen served as Corporate Vice President for Global Pharma Consulting and Business Development and member of the management team at NNE Pharmaplan A/S, an engineering and consulting company (part of Novo Nordisk A/S), from October 2014 to July 2015. From 1999 to September 2014, Mr. Jensen served as Executive Vice President of Product Supply (Production, Supply Chain, Engineering and Maintenance, Business Improvements, Quality Assurance and Health, Safety and Environment) and member of the Board of Management of ALK-Abello A/S, a pharmaceutical company. From 1986 to 1999, Mr. Jensen held several management positions relating to development, manufacturing and engineering within Novo Nordisk A/S. Mr. Jensen is also a member of various boards of directors of companies in the life sciences industry. Mr. Jensen holds a M.Sc. in Pharmacy from the University of Copenhagen.

Michael Wolff Jensen, L.L.M. has served as our Executive Vice President, Chief Legal Officer since January 2023 and previously served as our Senior Vice President, Chief Legal Officer from June 2013 until January 2023. Mr. Jensen also served as Chairman of the board of VISEN Pharmaceuticals until June 2025. In addition, Mr. Jensen served as Chairman of our board of directors from January 2008 to May 2021 and as our Acting Chief Financial Officer from May 2008 to June 2013. Prior to Ascendis Pharma, Mr. Jensen served as Executive Vice President & Chief Financial Officer of LifeCycle Pharma, currently known as Veloxis Pharmaceuticals A/S, a publicly traded biotechnology company, from 2003 to 2008. Prior to joining Veloxis, Mr. Jensen served as Senior Vice President & Chief Financial Officer of Genmab A/S from 2000 to 2003. Mr. Jensen received an L.L.M. degree from the University of Copenhagen.

Stina Singel, M.D., Ph.D. has served as our Executive Vice President, Head of Clinical Development, Oncology, since January 2023 and previously served as our Senior Vice President, Head of Clinical Development, Oncology, from January 2022 until January 2023 and as our Head of Clinical Development, Oncology, from May 2020 to January 2022. Prior to joining Ascendis, Dr. Singel served as Senior Vice President and Head of Clinical Development and Drug Safety at Nektar Therapeutics, a biopharmaceutical company, from April 2019 to May 2020. From March 2014 to April 2019, Dr. Singel held various positions of increasing responsibility at Genentech, a biotechnology company, ending her tenure as Senior Medical Director. From 2017 to 2019, Dr. Singel also served as an Adjunct Clinical Instructor at the Stanford University School of Medicine. Prior to Genentech, Dr. Singel was an Attending Physician and Clinical Translational Researcher focused on breast oncology at the University of Texas Southwestern Medical Center from 2010 to 2014 and was a Medical Oncologist at Washington Hematology Oncology, a community practice in Yakima, Washington, from 2008 to 2010. Dr. Singel received her M.D. and Ph.D. degrees from the University of California, San Diego, where she also completed her internal medicine residency and medical oncology fellowship. She received her B.S. in Biology (magna cum laude) from Harvard University.

Scott T. Smith has served as our Executive Vice President and Chief Financial Officer since January 2023 and previously served as our Senior Vice President and Chief Financial Officer from August 2016 until January 2023. Previously, Mr. Smith served as Director of the Healthcare Investment Banking Group at Wedbush Securities, from 2012 to 2016, where he led the healthcare team, and, from 2009 to 2012, Mr. Smith served as a Managing Director at Wedbush. Prior to joining Wedbush, Mr. Smith served as a Director in the Global Healthcare Investment Banking Group at Merrill Lynch where he began his career in 1995. He has also worked in sales, marketing and strategy roles for various companies, including start-ups and a Fortune Global 500 company. Mr. Smith received his M.B.A. from the Stanford University Graduate School of Business and graduated magna cum laude with a B.A. in Economics/Accounting-Physics from Claremont McKenna College.

Lotte Sønderbjerg has served as our Executive Vice President, Chief Administrative Officer since January 2023 and previously served as our Senior Vice President, Chief Administrative Officer from December 2007 until January 2023. Mrs. Sønderbjerg is also Managing Director of Ascendis Pharma GmbH. Prior to joining Ascendis, Mrs. Sønderbjerg served as Senior Director of Human Resources and as Finance Director at Veloxis Pharmaceuticals A/S from 2003 to 2007. Prior to joining Veloxis Pharmaceuticals A/S, Mrs. Sønderbjerg served as Senior Director of Finance and Human Resources at Acadia Pharmaceuticals Inc., a publicly traded biotechnology company, from 1996 to 2003. Prior to her career in biotech, Mrs. Sønderbjerg was the Executive Secretary for the CEO and Board of Directors of Novo Nordisk A/S and PA to leading audit partner in PricewaterhouseCoopers LLP in Denmark. Mrs. Sønderbjerg received a Masters of Arts in International Business Communications from University of Aarhus.

Kennett Sprogøe, Ph.D. has held positions of increasing responsibility at Ascendis Pharma since December 2007, including serving as our Executive Vice President, Head of Innovation and Research since January 2023, Senior Vice President, Head of Innovation and Research from 2019 until January 2023, Senior Vice President of Product Innovation since January 2016 and Vice President Product Innovation since June 2014. Prior to joining Ascendis, Dr. Sprogøe conducted research at the University of Copenhagen, where he applied novel hyphenated screening technologies to expedite discovery of drug leads from natural sources. Dr. Sprogøe holds a Ph.D. in Natural Products Chemistry from the University of Copenhagen and a M.Sc. in Pharmacy from the Danish University of Pharmaceutical Sciences.

Aimee Shu, M.D. has served as Executive Vice President of Endocrine and Rare Disease Medical Sciences and Chief Medical Officer since November 2024 after holding positions of increasing responsibility since joining the Company in July 2017. These include Vice President and Head of Clinical Development, Endocrinology from May 2022 to November 2024, Vice President, Clinical Development, Endocrine Medical Sciences from January 2021 to November 2024, Senior Medical Director, Clinical Development from January 2019 to December 2020 and Medical Director, Clinical Development from July 2017 to December 2018. Dr. Shu has also served as Clinical Associate Professor of Medicine, Division of Endocrinology at Stanford University School of Medicine since November 2016 and has held positions of increasing responsibility at Stanford since November 2012, including Associate Program Director, Endocrinology Training Fellowship Training Program from July 2015 to July 2017 and Clinical Assistant Professor of Medicine, Division of Endocrinology from November 2012 to October 2016. Prior to 2012, Dr. Shu served as Assistant Professor of Medicine, Division of Endocrinology at Baylor College of Medicine from February 2011 to December 2011 and as Assistant Professor of Clinical Medicine at Columbia University College of Physicians & Surgeons from July 2009 to June 2010. Dr. Shu received her A.B. from Princeton University and her M.D. from Harvard Medical School before completing her residency at Brigham and Women's Hospital and a Fellowship in Endocrinology at Columbia University Medical Center.

Jay Donovan Wu has served as Executive Vice President and U.S. President at Ascendis Pharma since January 2025. Prior to joining Ascendis, Mr. Wu served in various positions of increasing responsibility at Genentech, Inc., a biotechnology company, from July 2012 to January 2025, ending his tenure as Vice President, Head of Rare Diseases Portfolio. Prior to this, Mr. Wu served as a Consultant at Bain & Company. Mr. Wu received a BA in Neuroscience and a BSEc in Finance from the University of Pennsylvania, Wharton School and an MBA from Stanford Graduate School of Business.

Mads Bodenhoff has served as Senior Vice President, Head of Finance and Principal Accounting Officer at Ascendis Pharma since March 2024. Mr. Bodenhoff served as Senior Vice President and Head of Finance of the Company from June 2021 to March 2024. From March 2018 to June 2021, Mr. Bodenhoff served as Chief Financial Officer at NKT Photonics A/S. From September 2014 to February 2018, Mr. Bodenhoff served as Chief Financial Officer at Xellia Pharmaceuticals, a subsidiary of Novo Holdings A/S. From 2007 to 2014, Mr. Bodenhoff served as Vice President Finance and Vice President Corporate Finance at Novozymes A/S, a global biotechnology company. Prior to this, Mr. Bodenhoff had leading financial roles for Novozymes within China and Asia Pacific and Latin and North America. Mr. Bodenhoff currently serves on the board of 4XROBOTS A/S and Optheras A/S. Mr. Bodenhoff received a Bachelor in Economics from Handelshøjskolen in Slagelse and a Master's Degree in Business Economics and Auditing from Copenhagen Business School. Mr. Bodenhoff further is educated as a state authorized public accountant in Denmark.

B. Compensation

Compensation of Members of Our Board of Directors and Senior Management

The primary objective of our board of directors and senior management (executive board and non-executive senior management) compensation program is to attract, motivate, reward and retain the managerial talent needed to achieve our business objectives. In addition, the compensation program is intended to compensate all employees at competitive market rates, while recognizing extraordinary accomplishments.

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

Compensation to our senior management comprises salaries, participation in annual bonus schemes, pensions (defined contributions plans), and share-based compensation. Compensation to our board of directors comprises fees and salaries for their membership of the board and committee work, as applicable, and share-based compensation. Mr. Mikkelsen did not receive any separate compensation in respect of his service on the board. Share-based compensation is elaborated in further details in Note 8, "Share-based Payment."

Compensation cost to the board of directors and senior management is summarized below:

	Board of Directors [1]			Executive Board [2]			Non-executive Senior Management		
(EUR'000)	2025	2024	2023	2025	2024	2023	2025	2024	2023
Compensation									
Wages and salaries	442	482	543	5,466	4,148	4,375	6,466	3,286	4,673
Share-based payment	2,425	2,169	1,276	18,568	18,334	13,243	14,464	10,266	9,529
Pensions (defined contribution plans)	—	—	—	73	57	54	136	98	122
Social security costs	—	—	—	598	118	103	316	52	45
Other employee cost	—	—	—	20	20	20	40	25	40
Total compensation	**2,867**	**2,651**	**1,819**	**24,725**	**22,677**	**17,795**	**21,422**	**13,727**	**14,409**

(1) The Board of Directors comprised six members for all years presented.

(2) The Executive Board comprised four members for all years presented.

Wages and salaries for our senior management set forth in the table above includes bonuses of €5.8 million, €3.0 million and €3.9 million for the years ended December 31, 2025, December 31, 2024 and December 31, 2023.

On March 1, 2025, our board of directors granted an aggregate of 15,520 Restricted Stock Units ("RSUs") to certain non-employee board members of the company and 122,915 RSUs to certain members of senior management. The aggregate grant date fair value of the RSUs granted was €20.8 million. Also on March 1, 2025, our board of directors granted an aggregate of 73,583 Performance Stock Units ("PSUs") to certain members of senior management. The aggregate grant date fair value of the PSUs was €11.1 million. As of December 31, 2025, a total of 33,491 RSUs and 270,950 RSUs were outstanding for non-employee board members and members of senior management, respectively, and a total of 162,843 PSUs were outstanding for members of senior management.

As of December 31, 2025, a total of 127,886 warrants and 1,575,143 warrants were outstanding for non-employee board members and members of senior management, respectively. On January 14, 2025, our board of directors granted 45,078 warrants to a new non-executive member of senior management with an exercise price per share of $131.57 (€128.42). The aggregate fair value of the warrants granted was €2.8 million.

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, 2025 was €0.

Senior Management Agreements

We have entered into employment or service agreements with our senior management, which are subject to termination and/or notice periods. Mr. Mikkelsen's employment agreement contains a notice period of six months if terminated by Mr. Mikkelsen and twelve months if terminated by Ascendis Pharma. In addition, in case of a change of control ("change in control period"), Ascendis Pharma would for a period of 12 months have to observe an 18 months' notice period. Should the position and responsibilities be changed during such change of control period (excluding insignificant changes) Mr. Mikkelsen will be entitled to regard his employment as having been terminated by Ascendis Pharma with twelve months' notice.

The agreements with certain members of senior management contain post-termination non-competition covenants that generally may last for a period of twelve months post-termination and entitle the executives to their base salary, or portion thereof, during the period.

Warrant Incentive Program

For information on our warrant incentive program, see Note 8, "Share-based Payment."

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 December 31, 2025.

Name	Grant Date	Awards granted and outstanding	Awards granted and outstanding, but unvested as of March 1, 2025		Award Exercise Price(s)	Award Expiration Date
Jan Møller Mikkelsen	December 14, 2016	94,000	—	€	19.42	December 14, 2026
	December 12, 2017	200,000	—	€	31.60	December 12, 2027
	December 11, 2018	200,000	—	€	54.64	December 11, 2028
	December 10, 2019	120,000	—	€	97.50	December 10, 2029
	December 10, 2020	101,145	—	€	145.50	December 10, 2030
	December 9, 2021	69,466	—	€	123.46	December 9, 2031

RSU Program and PSU Program

For information of our RSU and PSU programs, refer to Note 8, "Share-based Payment."

Insurance and Indemnification

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

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

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

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

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

C. Board Practices

Board of Directors

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

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

The general meeting of shareholders must elect no fewer than three and no more than ten members to our board of directors. The members of our board of directors are elected for a term expiring at the first annual general meeting following their election.

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

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

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

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

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

Mr. Mikkelsen is a member of our senior management and a member of our board of directors and has an employment agreement that provides for benefits upon termination of employment in certain circumstances. For information about such agreements, see "Item 6 B. Directors, Senior Management and Employees—Compensation—Senior Management Agreements."

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

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.

Director Independence

Our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise their ability to exercise independent judgement in carrying out the responsibilities of a director. As a result of this review, our board of directors determined that Lisa Bright, Albert Cha, M.D., Ph.D., William Carl Fairey Jr., Lars Holtug, and Siham Imani, representing five of our six directors, are "independent directors" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of Nasdaq. In making such determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining the director's independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities (if any).

Committees of the Board of Directors

We have an audit committee, a remuneration committee and a nominating and corporate governance committee. We have adopted a charter for each of these committees. Under Danish corporate law, it is not possible to delegate the decision-making authority of the entire board of directors to board committees.

Audit Committee

Our audit committee consists of Lars Holtug (Chair), Lisa Bright and William Carl Fairey Jr. Each member satisfies the independence requirements of the Nasdaq listing standards, and Lars Holtug qualifies as an "audit committee financial expert," as defined in Item 16A(b) of Form 20-F and as determined by our board of directors. Our audit committee oversees our accounting and financial reporting processes and the audits of our consolidated financial statements. As a foreign private issuer, we are not required to have a formal written audit committee charter that complies with Nasdaq Rule 5605(c)(1) and, although we have adopted an audit committee charter, we comply with home country practices in lieu of Nasdaq Rule 5605(c)(1). Nasdaq Rule 5605(c)(2)(A) requires that U.S. listed companies have an audit committee composed of at least three members, each of whom is an independent director, as defined in the Nasdaq rules. As a foreign private issuer, we are exempt from complying with the Nasdaq requirement to have an audit committee with at least three members, and we comply with home country practices in lieu of Nasdaq Rule 5605(c)(2)(A). However, our audit committee currently comprises three members, all of whom meet the relevant criteria for independence under Nasdaq rules and under Rule 10A-3 of the Exchange Act. Our audit committee is responsible for, among other things:

- making recommendations to our board of directors regarding the appointment by the general meeting of shareholders of our independent auditors;
- overseeing the work of the independent auditors, including making recommendations to the board of directors and resolving disagreements between the executive board and the independent auditors relating to financial reporting;
- reviewing the independence and quality control procedures of the independent auditors;
- discussing material off-balance sheet transactions, arrangements and obligations with the executive board and the independent auditors;
- reviewing all proposed related-party transactions;
- discussing the annual audited consolidated and statutory financial statements with the executive board;
- annually reviewing and reassessing the adequacy of our audit committee charter;
- meeting separately with the independent auditors to discuss critical accounting policies, recommendations on internal controls, the auditor's engagement letter and independence letter and other material written communications between the independent auditors and the executive board; and
- attending to such other matters as are specifically delegated to our audit committee by our board of directors from time to time.

Remuneration Committee

Our remuneration committee consists of Albert Cha, M.D., Ph.D. (Chair), Lisa Bright and Lars Holtug. Each member satisfies the independence requirements of the Nasdaq listing standards. Our remuneration committee assists our board of directors in reviewing and approving or recommending our compensation structure, including all forms of compensation relating to our board of directors and the executive board. As a foreign private issuer, we are not required to have a formal written remuneration committee charter that complies with Nasdaq Rule 5605(d)(1) and, although we have adopted a remuneration committee charter, we comply with home country practices in lieu of Nasdaq Rule 5605(d)(1). Our remuneration committee is responsible for, among other things:

- reviewing and making recommendations to our board of directors with respect to compensation of our executive board and members of our board of directors;

- reviewing and approving the compensation, including equity compensation, change-of-control benefits and severance arrangements, of our chief executive officer, chief financial officer and such other members of our executive board as it deems appropriate;
- overseeing and making recommendations to our board of directors regarding the evaluation of our executive board;
- reviewing periodically and making recommendations to our board of directors with respect to any incentive compensation and equity plans, programs or similar arrangements; and
- attending to such other matters as are specifically delegated to our remuneration committee by our board of directors from time to time.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Albert Cha, M.D., Ph.D. (Chair), Lisa Bright and Siham Imani. Each member satisfies the independence requirements of the Nasdaq listing standards. Our nominating and corporate governance committee assists the board of directors in selecting individuals qualified to become our board members and in determining the composition of the board of directors and its committees. Our nominating and corporate governance committee is responsible for, among other things:

- recommending to our board of directors, persons to be nominated for election or re-election to our board of directors at any meeting of the shareholders;
- overseeing orientation of new members of our board of directors, continuing education for existing members, and succession planning for our board of directors, leadership roles on our board of directors and its committees, and members of our senior management;
- overseeing our board of director's annual review of its own performance and the performance of its committees; and
- considering, preparing and recommending to our board of directors a set of corporate governance guidelines.

For information on the current term of office and the period during which the members of our board of directors, executive board and our senior management have served in office, see "Item 6 A. Directors, Senior Management and Employees—Directors and Senior Management."

D. Employees

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

	Selling, General, and Administration [1]	Research and Development, and Commercial Manufacturing	Total
December 31, 2025			
Europe	338	430	768
North America	322	99	421
Total	**660**	**529**	**1,189**

	Selling, General, and Administration [1]	Research and Development, and Commercial Manufacturing	Total
December 31, 2024			
Europe	253	413	666
North America	239	112	351
Total	**492**	**525**	**1,017**

	Selling, General, and Administration [1]	Research and Development	Total
December 31, 2023			
Europe	169	385	554
North America	185	140	325
Total	**354**	**525**	**879**

(1) Selling, general, and administration function includes commercial activities, corporate activities and business development.

In 2025, the number of employees engaged with selling, general, and administration increased, primarily due to commercial activities, and extension of corporate functions to support those activities. Further, in connection with formation of Eyconis, a separate company, certain employees of Ascendis Pharma, engaged with research and development in the U.S., joined the newly formed company in 2024. See "Item 7 B. Major Shareholders and Related Party Transactions—Related Party Transactions" for more information about Eyconis.

Ascendis has no collective bargaining agreements with labor unions. Employees, however, have full freedom to join a union if they choose and in certain European countries, employees are covered under collective bargaining agreement terms. We consider our employee relations to be good.

E. Share Ownership

See "Item 7 A. Major Shareholders and Related Party Transactions—Major Shareholders." Our board of directors and employees are eligible to own shares of the company through a warrant incentive program and a RSU and PSU program. For information on the programs, see Note 8, "Share-based Payment." For information regarding the warrants held by 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 December 31, 2025, see "Item 6 B. Compensation."

F. Disclosure of a Registrant's Action to Recover Erroneously Awarded Compensation

Not applicable.

Item 7 Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth information relating to the beneficial ownership of our shares as of December 31, 2025, 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 December 31, 2025, 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 61,977,408 ordinary shares outstanding as of December 31, 2025, which includes 597,096 ordinary shares represented by ADSs held by Ascendis Pharma A/S. Ordinary shares that a person has the right to subscribe for within 60 days of December 31, 2025 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights but are not deemed outstanding for purposes of computing the percentage ownership of any other person. Additionally, a person is considered to have the right to subscribe for ordinary shares which are subject to outstanding warrants and vested within 60 days of December 31, 2025, although such warrants may only be exercised in prescribed exercise periods. A person is considered to beneficially own ordinary shares which are subject to (i) RSUs that vest within 60 days of December 31, 2025 and (ii) the PSUs that vest on March 1, 2026; however, a person is not considered to beneficially own ordinary shares subject to any other PSUs because these awards are subject to performance-based vesting criteria which have not been achieved. None of our shareholders has different voting rights from other shareholders. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Ascendis Pharma A/S, at Tuborg Boulevard 12, DK-2900 Hellerup, Denmark.

Name and Address of Beneficial Owner	Number of Outstanding Shares Beneficially Owned	Number of Warrants Exercisable and RSUs/PSUs to be Settled Within 60 Days	Number of Shares Beneficially Owned	Percentage of Beneficial Ownership
Entities affiliated with RA Capital Management, L.P. [1]	9,710,428	—	9,710,428	15.7%
Westfield Capital Management Company, LP [2]	5,185,696	—	5,185,696	8.4%
Avoro Capital Advisors LLC [3]	4,988,888	—	4,988,888	8.0%
Entities affiliated with FMR LLC [4]	4,646,943	—	4,646,943	7.5%
Entities affiliated with Janus Henderson Group plc [5]	4,323,059	—	4,323,059	7.0%
Entities affiliated with Artisan Partners LP [6]	3,225,885	—	3,225,885	5.2%
Capital International Investors [7]	3,109,225	—	3,109,225	5.0%
Senior Management and Board Members				
Jan Møller Mikkelsen [8]	453,403	871,471	1,324,874	2.1%
Jethro Ekuta, D.V.M., Ph.D.	—	8,633	8,633	*
Sherrie Glass, MPA	—	9,394	9,394	*
Flemming Steen Jensen	11,388	102,608	113,996	*
Michael Wolff Jensen, L.L.M.	—	112,608	112,608	*
Stina Singel, M.D., Ph.D.	—	90,008	90,008	*
Scott T. Smith	4,017	182,608	186,625	*
Lotte Sønderbjerg	11,388	147,608	158,996	*
Kennett Sprogøe, Ph.D.	12,498	132,921	145,419	*
Aimee Shu, M.D.	1,917	19,287	21,204	*
Jay Donovan Wu	—	13,874	13,874	*
Mads Bodenhoff	—	43,061	43,061	*
Albert Cha, M.D., Ph.D.	2,158	21,090	23,248	*
Lisa Bright	—	43,653	43,653	*
William Carl Fairey Jr.	897	10,597	11,494	*
Lars Holtug, M.Sc.	2,664	55,548	58,212	*
Siham Imani	1,097	10,597	11,694	*

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

(1) Consists of 9,710,428 ADSs held by RA Capital Healthcare Fund, L.P. (the "RA Fund") as reported by Amendment No. 15 to Schedule 13G filed with the SEC on November 14, 2024 by RA Capital Management, L.P. ("RA Capital"). RA Capital Healthcare Fund GP, LLC is the general partner of the RA Fund. The general partner of RA Capital is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are the controlling persons. RA Capital serves as investment adviser for the RA Fund and may be deemed a beneficial owner of ADSs held by the RA Fund. The RA Fund has delegated to RA Capital the sole power to vote and the sole power to dispose of all securities held in the RA Fund's portfolio. Because the RA Fund has divested voting and investment power over the reported securities it holds and may not revoke that delegation on less than 61 days' notice, the RA Fund disclaims beneficial ownership of the securities it holds and therefore disclaims any obligation to report ownership of the reported securities. As managers of RA Capital, Dr. Kolchinsky and Mr. Shah may be deemed beneficial owners of the ADSs beneficially owned by RA Capital. The address of the RA Fund, the RA Capital, Dr. Kolchinsky and Mr. Shah is c/o RA Capital Management, L.P., 200 Berkeley Street, 18th Floor, Boston, MA 02116.

(2) Consists of 5,185,696 ADSs owned of record by clients of Westfield Capital Management Company, L.P. ("Westfield") in its capacity as investment advisor, as reported by Amendment No. 4 to Schedule 13G filed on February 11, 2026, by Westfield. Westfield's clients have the right to receive, or the power to direct the receipt of, dividends or proceeds from the sale of the shares. The address of Westfield is 1 Financial Center, 24th Floor, Boston, MA 02111.

(3) Consists of 4,988,888 ADSs held by Avoro Capital Advisors LLC ("Avoro") as reported on Amendment No. 2 Schedule 13G filed on November 14, 2024, by Avoro and Behzad Aghazadeh ("Dr. Aghazadeh"). Dr. Aghazadeh is the portfolio manager and controlling person of Avoro. The address of Avoro is 110 Greene Street, Suite 800, New York, NY 10012

(4) Consists of an aggregate of 4,646,943 ADSs beneficially owned, or that may be deemed to be beneficially owned, by FMR LLC, certain of its affiliates and other companies as reported on Amendment No. 11 to Schedule 13G filed on May 12, 2025, by FMR LLC. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. FMR LLC has its principal business office at 245 Summer Street, Boston, MA 02210.

(5) Consists of an aggregate of 4,323,059 ADSs beneficially owned, or that may be deemed to be beneficially owned, by Janus Henderson Group plc ("Janus Henderson") as reported on Amendment No. 8 to Schedule 13G filed on November 14, 2025. The address of Janus Henderson is 201 Bishopsgate, EC2M 3AE, United Kingdom.

(6) Consists of an aggregate of 3,225,885 ADSs beneficially owned, or that may be deemed to be beneficially owned, by Artisan Partners Limited Partnership ("APLP"), Artisan Investments GP LLC ("Artisan Investments"), Artisan Partners Holdings LP ("Artisan Holdings") and Artisan Partners Asset Management Inc. ("APAM") as reported by Amendment No. 6 to Schedule 13G filed on February 3, 2026. Artisan Holdings is the sole limited partner of APLP and the sole member of Artisan Investments; Artisan Investments is the general partner of APLP; APAM is the general partner of Artisan Holdings. APLP, Artisan Investments, Artisan Holdings and APAM have shared voting power over 2,883,433 shares and shared dispositive power over 3,225,885 shares. The address of APLP, Artisan Investments, Artisan Holdings, and APAM is 875 East Wisconsin Avenue, Suite 800, Milwaukee, WI 53202.

(7) Consists of an aggregate of 3,109,225 ADSs beneficially owned, or that may be deemed to be beneficially owned, by Capital International Investors ("Capital") as reported on Schedule 13G filed on August 13, 2025. The address of Capital is 333 South Hope Street, 55th Fl, Los Angeles, CA 90071.

(8) Consists of (i) 871,471 ordinary shares that may be subscribed pursuant to the exercise of warrants or that may vest pursuant to RSUs and PSUs within 60 days of December 31, 2025 by Mr. Mikkelsen and (ii) 453,403 ordinary shares and ADSs beneficially owned by Mr. Mikkelsen, of which 68,470 ordinary shares and ADSs are owned through an entity controlled by Mr. Mikkelsen and 183,187 ordinary shares and ADSs have been pledged as security to lending financial institutions.

Significant Changes in Ownership

To our knowledge, other than as disclosed in the table above, our other filings with the SEC and this Annual Report, there has been no significant change in the percentage ownership held by any major shareholder during the past three years.

Record Holders

As of December 31, 2025, assuming that all of our ordinary shares represented by ADSs are held by residents of the United States, 99.9% of our outstanding ordinary shares were held in the United States by two holders of record and 0.1% of our outstanding ordinary shares were held outside of the United States.

B. Related Party Transactions

The following is a description of related party transactions we have entered into since January 1, 2025 with any of our board members, our senior management, the owners of more than five percent of our share capital, and any other related parties.

Employment Agreements and Grants of Warrants and RSUs/PSUs

We have entered into employment agreements with, and granted RSUs and PSUs to, certain members of our senior management. Further, we have issued RSUs to our members of the board of directors. In addition, we are paying fees for board tenure and board committee tenure to the independent members of our board of directors. See "Item 6 B. Directors, Senior Management and Employees—Compensation" for more information.

Indemnification Agreements

We have entered into indemnification agreements with our board members and members of our senior management. See "Item 6 B. Directors, Senior Management and Employees—Compensation—Insurance and Indemnification" for a description of these indemnification agreements.

VISEN Pharmaceuticals

Research and development services to VISEN Pharmaceuticals ("VISEN") under our Rights Agreements are reimbursed by VISEN. Further, under our Rights Agreements, clinical supply agreements, purchase agreement and commercial supply agreement, we have provided and agreed to provide product supply to VISEN for use in Greater China.

For quantitative details regarding transactions and outstanding balances with associates, including VISEN, please refer to Note 13, "Investments in Associates."

Eyconis

On January 29, 2024, we announced the formation and launch with Frazier Life Sciences of Eyconis, a separate company created to develop, manufacture, and commercialize TransCon ophthalmology assets globally, together with a $150 million commitment from an investor syndicate that includes Frazier, RA Capital Management, venBio, and HealthQuest Capital. Albert Cha, M.D., Ph.D. the chairman of our board of directors, is a Managing Partner with Frazier Life Sciences and serves on an investment committee exercising control over Frazier Life Sciences Public Fund, L.P.; however, Frazier's investment in Eyconis was made by Frazier Life Sciences XI, L.P., whose investment committee does not include Dr. Cha. The audit committee of our board of directors reviewed the facts and circumstances of Dr. Cha's relationship with Frazier Life Sciences and has determined that Dr. Cha does not have a direct or indirect material interest in our transactions with Eyconis.

We have granted Eyconis exclusive rights to develop and commercialize TransCon ophthalmology products globally and received an equity position in the newly formed company. In addition, we are eligible to receive development, regulatory, and sales milestone payments, plus single digit royalties on global net sales of commercialized products, if any. Eyconis is based in Redwood City, California and certain employees of Ascendis joined the newly formed company in 2024.

In connection with the formation of Eyconis in 2024, we have provided various administrative and support services under our Transitional Services Agreement. Further, under our Inventory Transfer Agreement and Material Transfer Agreement, we have, in 2024, sold laboratory and office inventory, materials and assigned certain contract manufacturers contracts to Eyconis. In addition, under our Sublease Agreement, we have subleased R&D and laboratory facilities to Eyconis, initially until December 2025, and, which in 2025, was subsequently extended until April 2030.

For quantitative details regarding transactions and outstanding balances with associates, please refer to Note 13, "Investments in Associates."

C. Interests of Experts and Counsel

Not applicable.

Item 8 Financial Information

A. Consolidated Statements and Other Financial Information

See the financial statements beginning on page F-1.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. For an example, BioMarin has initiated certain legal proceedings aimed at delaying or preventing patient access to TransCon CNP. For further details, please refer to "Item 4B. Information on the Company – Business Overview – TransCon Technologies– Achondroplasia."

Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Dividends

We do not at present plan to pay cash dividends on our ordinary shares. Under Danish law, the distribution of ordinary and extraordinary dividends requires the approval of a company's shareholders at a company's general meeting. Under the Danish Companies Act the general meeting may authorize the board of directors to resolve to distribute extraordinary dividends after presentation of a company's first financial statements. The authorization may be subject to financial and time restrictions. 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. The decision to pay out extraordinary dividends shall be accompanied by a balance sheet. The board of directors determines 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 extraordinary dividend payment shall be prepared. If a resolution to distribute extraordinary dividends is passed more than six months after the balance sheet date as set out in the company's latest approved annual report an interim balance sheet showing that sufficient funds are available for distribution must always be prepared.

B. Significant Changes

See Note 23, "Subsequent Events" to the audited consolidated financial statements included elsewhere in this annual report.

Item 9 The Offer and Listing

A. Offer and Listing Details

The ADS have been listed on The Nasdaq Global Select Market under the symbol "ASND" since January 28, 2015. Prior to that date, there was no public trading market for ADSs or our ordinary shares.

B. Plan of Distribution

Not applicable.

C. Markets

The ADS have been listed on The Nasdaq Global Select Market under the symbol "ASND" since January 28, 2015.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10 Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The information required by this section, including a summary of certain key provisions of our articles of association, is set forth in Exhibit 2.3 (Description of Share Capital) filed as an exhibit to this Annual Report on Form 20-F and is incorporated herein by reference.

C. Material Contracts

Except as otherwise disclosed in this annual report (including the Exhibits), we are not currently party to any material contract, other than contracts entered into in the ordinary course of business.

D. Exchange Controls

The Danish Act on Foreign Investment Screening sets out rules on screening of certain foreign direct investments etc. in Denmark ("Danish FDI Rules"). Pursuant to the Danish FDI Rules, a screening mechanism applies to foreign direct investments in certain sensitive sectors where a foreign investor obtains at least 10% ownership or voting rights or equivalent control by other means. The purpose of the Danish FDI Rules is to prevent foreign direct investments and special economic agreements from posing a threat to national security or public order in Denmark, through screening and possible interventions against such investments and agreements. Among the sensitive sectors defined in the Danish FDI rules are companies and entities that are critical infrastructure in Denmark in relation to the production, registration, distribution, and monitoring of prescription drugs.

If a contemplated foreign direct investment in Ascendis Pharma A/S is considered to fall within the scope of the mandatory screening mechanism, the foreign investor is required to apply for prior authorization with the Danish Business Authority. FDI filings, notifications, or approvals may under certain circumstances also be required in non-Danish jurisdictions.

If a foreign investor fails to comply with the Danish FDI Rules, the Danish Business Authority may impose restrictions, including ordering the reversal of the investment or the suspension of the foreign investor's voting rights.

International trade and financial sanctions are continually evolving. If applicable, such international trade and financial sanctions may under certain circumstances prevent the possibility of export and import of capital, and affect the remittance of dividends, interest and other payments to non-resident holders of shares or ADS.

In addition, international trade and financial sanctions may restrict the right of non-resident or foreign owners to acquire, transfer, hold or vote the shares and ADS. Failure to comply with international trade and financial sanctions can lead to criminal and civil liability.

E. Taxation

Danish Tax Considerations

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

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

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

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

Tax Characterization of the ADSs

Under Danish tax law, ADSs may be qualified as shares or financial instruments depending on the specific terms of the ADS.

We obtained a tax ruling on June 21, 2022, from the Danish Tax Council which confirmed that ADSs issued by us are considered as shares for Danish tax purposes. Based on an analysis of the terms of the Deposit Agreement between 1) the holders of ADSs, 2) Ascendis Pharma A/S and 3) Bank of New York Mellon, the Danish Tax Council found that the voting and economic rights attached to the underlying shares had effectively been transferred to the ADS holders and therefore, the ADSs qualified as shares for Danish tax purposes. The ruling is binding on the Danish tax authorities for 5 years as long as the facts remain as described in the ruling for the duration of the 5-year period and in the absence of a change of law. The ruling further confirmed that the ADSs are to be considered listed shares, as the ADSs are listed on Nasdaq. Accordingly, the remainder of this Danish tax discussion assumes that the ADSs will be treated as listed shares for Danish tax purposes.

Taxation of Danish Tax Resident Holders of the ADSs

Sale of the ADSs (Individuals)

For individual investors in 2025, gains from the sale of shares are included in the computation of the annual share income subject to 27% tax on the first DKK 67,500 (for cohabiting spouses, a total of DKK 135,000) and at a rate of 42% on share income exceeding DKK 67,500 (for cohabiting spouses over DKK 135,000). Such amounts are subject to annual adjustment and include all share income (*i.e.*, all capital gains and dividends derived by the individual or cohabiting spouses, respectively). The realization principle applies; i.e. the gains or losses are included in the income in the year of disposal.

Gains and losses on the sale of shares are calculated as the difference between the purchase price and the sales price. The purchase price is generally determined using the average method (in Danish "gennemsnitsmetoden") as a proportionate part of the aggregate purchase price for all the shareholder's shares in the company.

As the ADSs, for the purpose of this tax description, are considered listed shares for Danish tax purposes, losses may be offset against received dividends and capital gains on listed shares. Unused losses will automatically be offset against a cohabiting spouse's dividends and capital gains on listed shares. Any unused losses can be carried forward. It is a requirement for offsetting of losses, that the ADS holder (or the ADS holder's custodian bank) has declared the acquisition of the shares in the tax return for the year of acquisition. Such declaration must specify the identity of the ADS, the number of ADS acquired, the acquisition sum and the date of acquisition.

Sale of the ADSs (Companies)

For the purpose of taxation of sales of shares made by corporate shareholders, a distinction is made between Subsidiary Shares, Group Shares, Tax-Exempt Portfolio Shares and Taxable Portfolio Shares (note that the ownership threshold described below is applied on the basis of the number of all shares issued by the company, and not on the basis of the number of the ADSs issued):

"Subsidiary Shares" are generally defined as shares owned by a shareholder holding at least 10% of the nominal share capital of the issuing company.

"Group Shares" are 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" are 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" are defined as shares that do not qualify as Subsidiary Shares, Group Shares or Tax-Exempt Portfolio Shares.

Gains or losses on disposal of Subsidiary Shares and Group Shares and Tax-Exempt Portfolio Shares are not included in the taxable income of the shareholder.

Special rules apply with respect to Subsidiary Shares and Group Shares to prevent exemption through certain pooling of ownership holding company structures just as other anti-avoidance rules may apply. These rules will not be described in further detail.

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

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

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

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.

Dividends (Individuals)

Dividends on listed shares are taxed as share income, as described above. All share income must be included when calculating whether the amounts described above are exceeded. Dividends paid to individuals are generally subject to 27% withholding tax.

Dividends (Companies)

For corporate investors, dividends paid on Subsidiary Shares, Group Shares and Tax-Exempt Portfolio Shares are tax-exempt irrespective of ownership period, if the investor is considered beneficial owner.

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

The withholding tax rate is 27% as a starting point, which can be reduced (to 0% or 22%) if certain requirements are met. A claim for repayment can be made by the shareholder to whom the company has distributed the dividends, within the calendar year in which the dividend distribution was approved or the excess tax will offset the corporation income tax for the year. The statute of limitations is three years.

Taxation of Shareholders Residing Outside Denmark

Based on a tax ruling on June 21, 2022, from the Danish Tax Council, holders of ADSs issued by Ascendis Pharma A/S are treated as holding listed ordinary shares in the company for Danish tax purposes.

Sale of the ADSs (Individuals and Companies)

Holders of the ADSs not resident in Denmark are normally not subject to Danish taxation on any gains realized on the sale of ADSs, irrespective of the ownership period, subject to certain anti-avoidance rules seeking to prevent that taxable dividend payments are converted to tax exempt capital gains.

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

If an investor holds the ADSs in connection with a trade or business conducted from a permanent establishment in Denmark, gains on shares may be included in the taxable income of such activities pursuant to the rules applying to Danish tax residents as described above.

Dividends (Individuals)

Dividends are generally subject to 27% Danish withholding tax. Individuals residing in certain black-listed countries and holding 25% or more of the share capital or the voting rights, or have within the past 5 years held 25 % or more of the share capital or voting rights in the company, are subject to 44% withholding tax.

Non-residents of Denmark are not subject to additional Danish income tax with respect to dividends received on shares.

Holders of ADSs are, as shareholders, entitled to apply for a full or partial refund of Danish withholding tax on dividends withheld by the company, in the situations described below.

Reduction According to a Tax Treaty

In the event that the ADS holder is a resident of a state with which Denmark has entered into a tax treaty, the holder 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%. Such a withholding tax reduction in accordance with a tax treaty, requires that the holder of the ADS is also considered beneficial owner of the dividends according to the applicable double tax treaty and that the tax residency of the ADS holder can be documented. Denmark has entered into tax treaties with approximately 80 countries, including the United States, Switzerland and almost all members of the European Union. The tax treaty between Denmark and the United States generally provides for a 15% tax rate.

Individuals residing in certain black-listed countries and holding 25% or more of the share capital or the voting rights, or have within the past 5 years held 25 % or more of the share capital or voting rights, in the company are not eligible for refund of dividend withholding taxes.

Reduction According to Danish Tax Law

If the ADS holder holds less than 10% of the nominal share capital (in the form of ordinary shares in the company and not on the basis of the number of the ADSs issued) of the company – through ownership of ordinary shares and ADS - and the ADS holder is tax resident in a state which has a tax treaty or an international agreement, convention or other administrative agreement on assistance in tax matters according to which the competent authority in the state of the ADS holder is obligated to exchange information with Denmark, dividends are subject to tax at a rate of 15%. If the ADS holder is tax resident outside the European Union, it is an additional requirement for eligibility for the 15% tax rate that the ADS holder together with related parties holds less than 10% of the nominal share capital of the company.

Note that the reduced tax rate does not affect the withholding rate, which is why the holder must claim a refund as described above in order to benefit from the reduced rate.

Where a non-tax 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.

Individuals residing in certain black-listed countries and holding 25% or more of the share capital or the voting rights, or have within the past 5 years held 25 % or more of the share capital or voting rights, in the company are not eligible for refund of dividend withholding taxes.

Dividends (Companies)

Dividends paid to companies are generally subject to 27% withholding tax.

Companies residing in certain black-listed countries and holding Subsidiary Shares or Group Shares are subject to 44% withholding tax, unless it can be proved that the beneficial owner of the dividend is a resident of the European Union or the EEA or a state with which Denmark has entered into a tax treaty. Furthermore, such companies are not eligible for refund of dividend withholding taxes.

The withholding tax rate is reduced to zero for dividends from:

- Subsidiary Shares, provided that the taxation of the dividends is to be waived or reduced in accordance with the Parent-Subsidiary Directive (2011/96/EEC) or in accordance with a tax treaty with the jurisdiction in which the ADS holder, as shareholder, is resident. Thus, 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.
- Group Shares, not also being Subsidiary Shares, provided the ADS holder, as shareholder, 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 ADS holder is resident had the shares been Subsidiary Shares.
- Tax Exempt Portfolio shares provided that the ADS holder – as shareholder – is also considered the beneficial owner of the dividends and a tax resident in a state where the competent authority is obliged to exchange information with Denmark in accordance with a tax treaty, convention or other administrative agreement on assistance in tax matters.
    - For an ADS holder – as shareholder – tax resident in an EU member state or in an EEA state that has entered a tax treaty with Denmark, the above only applies if the ADS holder owns less than 10% of the share capital in the company.
    - For an ADS holder – as shareholder – tax resident outside an EU member state or an EEA state that has entered a tax treaty with Denmark, the above only applies if the ADS holder together with associated parties own less than 10% of the share capital in the company.
    - Further, if the beneficial owner of the dividends is not tax resident in an EU member state or if Denmark is not obliged to reduce taxation of the dividends according to a tax treaty, the above only applies if the beneficial owner does not have controlling influence (broadly defined) in the company.

Dividends paid on Taxable Portfolio Shares are generally subject to tax at a rate of 22% irrespective of ownership period. While the actual withholding tax rate is as a starting point 27%, it can be reduced if certain requirements are met.

If the withholding tax levied is higher than the final withholding tax rate in accordance with the above, the ADS holder – as shareholder - may generally, through certain certification procedures, seek a refund from the Danish tax authorities of the tax withheld in excess of the applicable rate, to the extent the tax residency of the ADS holder and any additional requirements, inter alia beneficial ownership and ownership percentage, can be documented

Further, in the event that the ADS holder is considered beneficial owner of the dividends and is a resident of a state with which Denmark has entered into a tax treaty, the holder 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, to the extent the tax residency of the ADS holder can be documented. Denmark has entered into tax treaties with approximately 80 countries, including the United States and almost all members of the European Union. The tax treaty between Denmark and the United States generally provides for a 15% rate.

Non-residents of Denmark are not subject to additional Danish income tax with respect to dividends received on shares

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

Share Transfer Tax and Stamp Duties

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

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

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

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

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons whose functional currency is not the U.S. dollar;
- persons holding the ADSs as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities, commodities or currencies;
- partnerships, S corporations or other entities or arrangements treated as partnerships or pass-through entities for U.S. federal income tax purposes, and persons that hold ADSs through such entities or arrangements;
- tax-exempt organizations, "individual retirement accounts" or "Roth IRAs";
- governmental organizations;
- persons who acquired the ADSs pursuant to the exercise of any employee share option or otherwise as compensation;
- persons that own or are deemed to own 10% or more of the company's equity by vote or value;
- persons that hold their ADSs through a permanent establishment or fixed base outside the United States; and
- persons deemed to sell the ADSs under the constructive sale provisions of the Code.

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

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

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized under the laws of the United States, any state thereof or the District of Columbia;

- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code) or (2) has a valid election in effect under applicable Treasury Regulations to be treated as a United States person for U.S. federal income tax purposes.

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

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

Taxation of Dividends and Other Distributions on the ADSs

Subject to the passive foreign investment company, or PFIC, rules discussed below, the gross amount of any distribution to you with respect to the ADSs will be included in your gross income as dividend income when actually or constructively received to the extent that the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent the amount of the distribution exceeds our current and accumulated earnings and profits, it will be treated first as a return of your tax basis in the ADSs, and to the extent the amount of the distribution exceeds your tax basis, the excess will be taxed as capital gain. However, 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, or if the ADSs are readily tradable on an established securities market in the United States, 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. ADSs representing ordinary shares generally are considered for these purposes to be readily tradable on an established securities market in the United States if they are listed on The Nasdaq Global Select Market, as our ADSs currently are. You should consult your tax advisor regarding the availability of these preferential tax rates under your particular circumstances.

As discussed above in "Taxation—Danish Tax Considerations," payments of dividends by us may be subject to Danish withholding tax. The rate of withholding tax applicable to U.S. Holders that are eligible for benefits under the Treaty is reduced to a maximum of 15%.

For U.S. federal income tax purposes, U.S. Holders will be treated as having received the amount of withheld Danish taxes, and as then having paid over the withheld taxes to the Danish taxing authorities. As a result of this rule, the amount of dividend income included in gross income for U.S. federal income tax purposes by a U.S. Holder with respect to a payment of dividends may be greater than the amount of cash actually received (or receivable) by the U.S. Holder from us with respect to the payment.

Dividends will generally constitute foreign-source income for foreign tax credit limitation purposes. Subject to the discussion of the PFIC rules below, any tax withheld with respect to distributions on the ADSs at the rate applicable to a U.S. Holder may, subject to a number of complex limitations, be claimed as a foreign tax credit against such U.S. Holder's U.S. federal income tax liability or may be claimed as a deduction for U.S. federal income tax purposes. Any amount withheld in excess of the tax rate applicable to a U.S. Holder generally is not eligible to be claimed as a foreign tax credit, regardless of whether such amount is actually refunded or reclaimed. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to the ADSs generally will constitute "passive category income." Certain Treasury Regulations may restrict the availability of a foreign tax credit based on the nature of the tax imposed by the foreign jurisdiction. However, under current IRS guidance, taxpayers generally may elect to determine the creditability of foreign taxes without regard to such restrictions for taxable years ending prior to the year further guidance is issued. The rules with respect to the foreign tax credit are complex and involve the application of rules that depend upon a U.S. Holder's particular circumstances. You are urged to consult your tax advisor regarding the availability of the foreign tax credit under your particular circumstances.

Taxation of Disposition of the ADSs

Subject to the PFIC rules discussed below, you will recognize gain or loss on any sale, exchange or other taxable disposition of an ADS equal to the difference between the amount realized (in U.S. dollars) on the disposition of the ADS and your tax basis (in U.S. dollars) in the ADS. Any such gain or loss will be capital gain or loss, and will be long-term capital gain or loss if you have held the ADS for more than one year at the time of sale, exchange or other taxable disposition. Otherwise, such gain or loss will be short-term capital gain or loss. Long-term capital gains recognized by certain non-corporate U.S. Holders, including individuals, generally will be taxable at a reduced rate. The deductibility of capital losses is subject to limitations. Any such gain or loss you recognize generally will be treated as U.S.-source income or loss for foreign tax credit limitation purposes. You should consult your tax advisor regarding the proper treatment of gain or loss in your particular circumstances.

Passive Foreign Investment Company

Under the Code and Treasury Regulations, the determination of PFIC status is fact-specific and cannot be made until after the close of the taxable year in question. Based on our market capitalization and the composition of our income, assets and operations, we do not believe we were a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2025. However, this is a factual determination, and the application of the PFIC rules is subject to uncertainty in several respects, and we cannot assure you we will not be a PFIC for any taxable year. A non-U.S. corporation will be considered a PFIC for any taxable year if either:

- at least 75% of its gross income for such taxable year is passive income (as defined in the relevant provisions of the Code), or
- at least 50% of the value of its assets (generally based on an average of the quarterly values of the assets during such 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, including unbooked goodwill, for purposes of the asset test will generally be determined by reference to the market price of the ADSs, our PFIC status will depend in large part on the market price of the ADSs, which may fluctuate significantly. In addition, changes in the composition of our income or assets may cause us to become a PFIC. For these reasons, we cannot assure you we will not be a PFIC for any taxable year.

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

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

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

Gains (but not losses) realized on the sale of the ADSs cannot be treated as capital gains, even if you hold the ADSs as capital assets.

If we are treated as a PFIC with respect to you for any taxable year, to the extent we own directly or indirectly equity in any non-U.S. corporations that are also PFICs, you will be deemed to own your proportionate share of any such lower-tier PFIC, and you may be subject to the rules described in the preceding two paragraphs with respect to the shares of such lower-tier PFICs you would be deemed to own. As a result, you may incur liability for any "excess distribution" described above if we receive a distribution from such lower-tier PFICs or if any shares in such lower-tier PFICs are disposed of (or deemed disposed of). You should consult your tax advisor regarding the application of the PFIC rules to any lower-tier PFICs.

Alternatively, a U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a "mark-to-market" election for such stock to elect out of the general tax treatment for PFICs discussed above. If you make a "mark-to-market" election for the ADSs, you will include in income for each year we are a PFIC an amount equal to the excess, if any, of the fair market value of the ADSs as of the close of your taxable year over your adjusted basis in such ADSs. You are allowed a deduction for the excess, if any, of the adjusted basis of the ADSs over their fair market value as of the close of the taxable year. However, deductions are allowable only to the extent of any net "mark-to-market" gains on the ADSs included in your income for prior taxable years. Amounts included in your income under a "mark-to-market" election, as well as gain on the actual sale or other disposition of the ADSs, are treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any "mark-to-market" loss on the ADSs, as well as to any loss realized on the actual sale or disposition of the ADSs to the extent the amount of such loss does not exceed the net "mark-to-market" gains previously included for the ADSs. Your basis in the ADSs will be adjusted to reflect any such income or loss amounts. If you make a valid "mark-to-market" election, the tax rules that apply to distributions by corporations that are not PFICs would apply to distributions by us, except the lower applicable tax rate for qualified dividend income would not apply. If we cease to be a PFIC when you have a "mark-to-market" election in effect, gain or loss realized by you on the sale of the ADSs will be a capital gain or loss and taxed in the manner described above under "Taxation of Disposition of the ADSs."

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

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

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

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

Information Reporting and Backup Withholding

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

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

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

Additional Reporting Requirements

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

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the periodic reporting and other informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under the Exchange Act, we are required to file reports and other information with the SEC. Specifically, we are required to file annually a Form 20-F no later than four months after the close of each fiscal year, which is December 31. The SEC maintains a web site at www.sec.gov that contains reports, proxy and information statements, and other information regarding registrants that make electronic filings with the SEC using its EDGAR system. As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the furnishing and content of quarterly reports and proxy statements, and officers, directors and major shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. However, effective March 18, 2026, our directors and officers will be required to comply with the reporting obligations under Section 16(a) of the Exchange Act.

I. Subsidiary Information

Not applicable.

J. Annual Report to Security Holders

The Company intends to submit any annual report provided to security holders in electronic format as an exhibit to a report on Form 6-K.

Item 11 Quantitative and Qualitative Disclosures About Market Risk

Our activities expose us to market risks related to changes in foreign currency exchange rates and interest rates. We do not enter into derivative financial instruments to manage our exposure to such risks. Further, we are exposed to credit risk, liquidity risk and inflation risk. For a description of our exposure to market risks, credit risk and liquidity risk, refer to Note 18, "Financial Risk Management." Inflation affects us as our vendors may pass on any increased costs to us and accordingly increase our R&D expenses, SG&A expenses and cost of manufacturing. We do not believe that inflation had a material impact on our results of operation for the years ended December 31, 2025 and 2024.

Item 12 Description of Securities Other than Equity Securities

A. Debt Securities.

Not applicable.

B. Warrants and Rights.

Not applicable.

C. Other Securities.

Not applicable.

D. American Depositary Shares.

The Bank of New York Mellon, as depositary, registers and delivers American Depositary Shares, also referred to as ADSs. Each ADS represents one ordinary share (or a right to receive one ordinary share) deposited with The Bank of New York Mellon, London Branch, or any successor, as custodian for the depositary. Each ADS also represents any other securities, cash or other property which may be held by the depositary in respect of the depositary facility. The depositary's corporate trust office at which the ADSs are administered and its principal executive office is located at 240 Greenwich Street, New York, New York 10286.

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

Fees and Expenses

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

Persons depositing or withdrawing ordinary shares or ADSs must pay:	***For:***
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	• Issue of ADSs, including issues resulting from a distribution of ordinary shares or rights or other property
	• Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$0.05 (or less) per ADS	• Any cash distribution to you
A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the shares had been deposited for issue of ADSs	• Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to you
$0.05 (or less) per ADS per calendar year	• Depositary services
Registration or transfer fees	• Transfer and registration of ordinary shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	• Cable (including SWIFT), telex and facsimile transmissions (when expressly provided in the deposit agreement)
	• Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian have to pay on any ADS or share underlying an ADS, for example, share transfer taxes, stamp duty or withholding taxes	• As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	• As necessary

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

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

PART II

Item 13 Defaults, Dividend Arrearages and Delinquencies

Not applicable.

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

A. Material Modifications to the Rights of Securities Holders

Not applicable.

B. Use of Proceeds

Not applicable.

Item 15 Controls and Procedures

A. Disclosure Controls and Procedures

Our chief executive officer and principal financial and accounting officers, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of December 31, 2025, have concluded that based on the evaluation of these controls and procedures required by Rule 13a-15(b) of the Exchange Act, our disclosure controls and procedures were effective.

B. Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting.

Internal control over financial reporting is defined in rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the audited consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect material misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. This assessment was performed under the directions and supervision of our Chief Executive Officer and our principal financial and accounting officers and based on the criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission.

A material weakness is a control deficiency, or a combination of control deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected. These control deficiencies could result in a misstatement of the financial statement accounts or related disclosures that would result in a material misstatement in the annual or interim consolidated financial statements that would not be prevented or detected on a timely basis. Based on management's assessment of those criteria, management has concluded that the design and operating effectiveness of our internal control over financial reporting was effective as of December 31, 2025.

C. Attestation Report of the Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by Deloitte Statsautoriseret Revisionspartnerselskab, an independent registered public accounting firm, as stated in their report, which appears in Item 18 below.

D. Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the period covered by this annual report that have materially affected, or is reasonably likely to materially affect, internal control over financial reporting.

Item 16A Audit Committee Financial Expert

Mr. Lars Holtug, an independent director under Nasdaq Rule 5605(a)(2) and Rule 10A-3 of the Exchange Act and a member of the Audit Committee, qualifies as an "audit committee financial expert," as defined in Item 16A(b) of Form 20-F and as determined by our board of directors.

Item 16B Code of Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, members of our senior management and members of our board of directors, including those members of our senior management responsible for financial reporting. Our code of ethics is posted on our Company website at: http://www.ascendispharma.com. We will disclose any substantive amendments to the code of business conduct and ethics, or any waiver of its provisions, on our website. The reference to our website does not constitute incorporation by reference of the information contained at or available through our website.

Item 16C Principal Accountant Fees and Services

The following table sets forth, for each of the years indicated, the fees billed by our independent public accountants and the percentage of each of the fees out of the total amount billed by the accountants.

	Year ended December 31, 2025		Year ended December 31, 2024	
	(EUR'000)	%	(EUR'000)	%
Audit fees	840	99	811	77
Audit-related fees	11	1	147	14
Tax fees	—	—	91	9
Total	**851**	**100**	**1,049**	**100**

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

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

Tax Fees relate to the aggregate fees billed in each of the last two fiscal years for professional services rendered by the principal accountant for tax compliance, tax advice, and tax planning.

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

Pre-Approval Policies and Procedures for Non-Audit Services

Our Audit Committee has adopted a policy pursuant to which we will not engage our auditors to perform any non-audit services unless the audit committee pre-approves the service. Pursuant to this policy, our Audit Committee assesses and pre-approves all audit and non-audit services provided by our auditors.

Item 16D Exemptions from the Listing Standards for Audit Committees

Not applicable.

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

The table below is a summary of the shares repurchased by us during the 2025 fiscal year.

Date	Total Number of ADSs Purchased	Weighted Average Price Paid per ADS (US$)*	Total Number of ADSs Purchased as Part of Publicly Announced Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
March 1, 2025-March 31, 2025	119,148	$153.17	119,148	—

(1) On February 12, 2025, we announced that our Board of Directors authorized the repurchase of up to $18.25 million of our ADSs. The repurchase program had no expiration date.

On January 9, 2026, we also announced that our Board has also authorized a $120 million share repurchase program (the "Share Repurchase Program"). Purchases under the Share Repurchase Program may be made from time to time through a variety of methods, which may include open-market purchases, privately negotiated transactions, or other methods permitted under applicable securities laws. The timing and amount of any repurchases pursuant to the Share Repurchase Program will be determined based on market conditions, share price and other factors. The Share Repurchase Program does not require us to repurchase any specific number of shares, and may be modified, suspended or terminated at any time without notice.

Item 16F Change in Registrant's Certifying Accountant

None.

Item 16G Corporate Governance

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

- We do not intend to follow Nasdaq's quorum requirements applicable to meetings of shareholders. In accordance with Danish corporate law and generally accepted business practice, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders.

- We do not intend to follow Nasdaq's requirements regarding the provision of proxy statements for general meetings of shareholders. Danish corporate law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in Denmark. We intend to provide shareholders with an agenda and other relevant documents for the general meeting of shareholders.
- We do not intend to follow Nasdaq's requirements regarding shareholder approval for certain issuances of securities under Nasdaq Rule 5635. Pursuant to Danish corporate law, our shareholders have authorized our board of directors to issue securities including in connection with certain events such as the acquisition of shares or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us, rights issues at or below market price, certain private placements and issuance of convertible notes. We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act of 2002, the rules adopted by the SEC and Nasdaq's listing standards. As a Danish company not listed on a regulated market within the EU/EEA, we do not need to comply with the Danish corporate governance principles nor do we need to explain any deviation from these provisions in our Danish statutory annual report.
- We do not intend to follow Nasdaq's requirements regarding shareholder approval for all equity compensation plans. Generally, Nasdaq Rule 5635(c) requires each issuer to obtain shareholder approval of all equity compensation plans (including warrant incentive plans) and material amendments to such plans. However, pursuant to Nasdaq Rule 5615(a)(3), we have elected to follow our home country's practices (in this case, being Danish practices) in lieu of the requirements of Nasdaq Rule 5635(c). Our home country practices do not require us to obtain shareholders' approval for amendments to our existing warrant incentive program.

Effective March 18, 2026, members of our board of directors and our officers (as defined in Rule 16a-1(f) under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act) will be subject to the reporting obligations under Section 16(a) of the Exchange Act. Additionally, they are subject to the obligations to report changes in share ownership under Section 13 of the Exchange Act and related SEC rules, if applicable.

Item 16H Mine Safety Disclosure

Not applicable.

Item 16I Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Item 16J Insider Trading Policies

We have adopted an insider trading policy governing the purchase, sale, and other dispositions of our securities by directors, senior management, and employees. A copy of the insider trading policy is filed as an exhibit to this annual report.

Item 16K Cybersecurity

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to safeguard the confidentiality and integrity of the information we collect and process, prevent unauthorized access to our information technology ("IT") systems and data, and ensure availability of our IT systems and data according to defined business requirements. Our cybersecurity risk management program includes a cybersecurity incident response plan.

Our Information Security Policy for Global IT outlines the organizational responsibilities for maintaining a strong security posture for our IT systems and sets forth the IT security measures and controls that are required to be in place. This policy covers all IT systems that process Company information. Our Security Management team is responsible for ensuring internal security compliance and for managing IT vendors.

We have designed our security program around the International Organization for Standardization/International Electrotechnical Commission ("ISO/IEC") 27001 standard on a strategic and tactical level, while our operational program is maintained in accordance with the Center for Internet Security ("CIS") Critical Security Controls framework. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the ISO/IEC and CIS Controls standards as guides to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- Risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- A security team principally responsible for managing (1) our cybersecurity risk assessment processes; (2) our security controls; and (3) our response to cybersecurity incidents;
- An external and internal Security Operations Center (SOC) performing advanced threat detection and response across our environment.
- The use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- A defined process for registration, classification and escalation of any incidents to a named IT Incident Manager and incident response team, which includes relevant members of the IT management team, the compliance team, business process owners and potentially external vendors;
- Security awareness campaigns for Company employees via various channels (intranet, direct mail, screen savers, etc.); and
- Secure access control measures applied to critical IT systems, equipment and devices, designed to prevent unauthorized users, processes, and devices from accessing IT systems and data.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition.

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated the oversight of cybersecurity and other information technology risks to the executive board. The executive board oversees the Security Management team's implementation of our cybersecurity risk management program.

The executive board receives regular updates from the Security Management team on our cybersecurity risks. In addition, the Security Management team updates the executive board, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

The executive board reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also receives briefings from management on our cyber risk management program. Board members receive presentations on cybersecurity topics from our Security Management team.

Our Security Management team is chaired by the Chief Information Officer and includes the Global Head of Digitalization and Cyber Security, and is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our Security Management team's background includes experience in regulatory compliance, cloud computing and infrastructure, and cyber incident response.

Our Security Management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel, threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us, as well as alerts and reports produced by security tools deployed in our IT environment.

Our executive management that is part of the Corporate Management Group signs off on the overall strategic direction for IT security and ensures alignment with our overall business strategy.

We have established a dedicated Security Organization Unit to drive alignment across all key security functions within the company. This unit is chaired by the Chief Information Officer and includes representatives with oversight of critical areas such as IT Compliance, AI & Automation, Global Service Desk, Infrastructure, Integration, and Data Management.

It is the responsibility of the Security Organization Unit to approve the Company's IT security roadmap, ensure allocation and prioritization of resources, and to act as the escalation point for IT security matters.

A named IT Director is assigned the responsibility of maintaining IT security across our global organization. This responsibility includes defining and driving IT security roadmap initiatives, defining and implementing activities needed to drive an IT security awareness program, supporting the assessment of new IT systems and vendors, and acting as the leader and point person in the event of a major security incident.

Operational responsibility resides with the related product teams. The product teams are responsible for ensuring effective and updated security technologies are used in the day-to-day operational procedures, and for maintaining, operating and implementing applications and technologies securely across business areas within the Company.

PART III

Item 17 Financial Statements

See “Item 18 Financial Statements.”

Item 18 Financial Statements

ASCENDIS PHARMA A/S

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Deloitte.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Ascendis Pharma A/S

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated statements of financial position of Ascendis Pharma A/S and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of profit or (loss) and other comprehensive income or (loss), the consolidated statements of changes in equity, and the consolidated statements of cash flows for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with IFRS Accounting Standards as issued by the International Accounting Standards Board and as adopted by the European Union. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

Basis for Opinions

The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matter

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

Revenue and provisions – US commercial sales deductions – Refer to Notes 3 and 4 to the financial statements

Critical Audit Matter Description

In the United States (US), the Company has entered into pricing agreements that include commercial sales deductions such as prompt pay discounts, shelf stock adjustments and applicable sales rebates attributable to various commercial arrangements, managed healthcare organizations, government programs, and co-pay arrangements. As such, revenue recognition includes variable consideration in the form of commercial sales deductions related to these agreements. Provisions are recognized for the unsettled parts and are a source of significant estimation uncertainty which could have a material impact on reported revenue.

We identified US commercial sales deductions as a critical audit matter due to the significant measurement uncertainty involved in developing the estimates used for these provisions for unsettled sales deductions, as the provisions are based on payer channel mix, current contract prices under eligible programs and current inventory levels in the distribution channels. In addition, significant judgments are involved in determining whether a significant reversal in the amount of revenue recognized will occur due to commercial arrangements generally being settled within 180 days of the transaction date. This led to significant auditor judgment, effort and subjectivity in applying procedures relating to the Company's estimate of these provisions.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to US commercial sales deductions included the following, among others:

- We tested the effectiveness of controls over US commercial sales deductions, including controls over the assumptions and data used to estimate these deductions;
- We evaluated whether the accounting treatment of US commercial sales deductions is consistent with the relevant accounting standards and the appropriateness of the Company's methodology to develop the estimates used for their commercial sales deductions provisions based on payer channel mix, current contract prices under eligible programs and current inventory levels in the distribution channels;

- We selected a sample of US commercial sales deductions claims processed by the Company, and evaluated those claims for consistency with the conditions and terms of the Company's commercial and governmental pricing agreements;
- We tested the overall reasonableness of the US commercial sales deductions provisions recorded at period-end by developing an independent expectation and comparing our expectation to the amount recorded by management, and
- We evaluated the Company's ability to estimate US commercial sales deductions accurately by considering the historical accuracy of the Company's estimates in the prior year compared to the actual claims information received in the current year.

/s/ Deloitte Statsautoriseret Revisionspartnerselskab

Copenhagen, Denmark

February 11, 2026

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

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

(EUR'000, except per share data)	Notes	2025	2024	2023
Consolidated Statement of Profit or (Loss)				
Revenue	**4**	720,132	363,641	266,718
Cost of sales	**7, 12**	(94,915)	(44,258)	(44,395)
Gross profit		**625,217**	**319,383**	**222,323**
Research and development expenses	**7, 12**	(303,621)	(307,004)	(413,454)
Selling, general, and administrative expenses	**7, 12**	(457,867)	(291,142)	(264,410)
Operating profit/(loss)		**(136,271)**	**(278,763)**	**(455,541)**
Share of profit/(loss) of associates	**13**	16,308	(20,060)	(18,395)
Finance income	**17**	113,999	25,609	43,857
Finance expenses	**17**	(206,687)	(100,027)	(44,065)
Profit/(loss) before tax		**(212,651)**	**(373,241)**	**(474,144)**
Income taxes (expenses)	**10**	(15,383)	(4,843)	(7,303)
Net profit/(loss) for the year		**(228,034)**	**(378,084)**	**(481,447)**
Attributable to owners of the Company		(228,034)	(378,084)	(481,447)
Basic earnings/(loss) per share	**5**	€ (3.76)	€ (6.53)	€ (8.55)
Diluted earnings/(loss) per share	**5**	€ (3.76)	€ (6.53)	€ (8.55)
Consolidated Statement of Comprehensive Income or (Loss)				
Net profit/(loss) for the year		**(228,034)**	**(378,084)**	**(481,447)**
Other comprehensive income/(loss)				
Items that may be reclassified subsequently to profit or (loss):				
Exchange differences on translating foreign operations		(3,538)	1,062	(2,731)
Other comprehensive income/(loss) for the year, net of tax		**(3,538)**	**1,062**	**(2,731)**
Total comprehensive income/(loss) for the year, net of tax		**(231,572)**	**(377,022)**	**(484,178)**
Attributable to owners of the Company		(231,572)	(377,022)	(484,178)

Consolidated Statements of Financial Position as of

(EUR'000)	Notes	December 31, 2025	December 31, 2024
Assets			
Non-current assets			
Intangible assets	**6, 11**	3,710	4,028
Property, plant and equipment	**6, 12**	146,479	98,714
Investments in associates	**13**	32,526	13,575
Other receivables	**17**	10,870	2,317
		193,585	**118,634**
Current assets			
Inventories	**14**	301,533	295,609
Trade receivables	**17**	141,333	166,280
Income tax receivables		1,781	1,775
Other receivables	**17**	14,582	9,385
Prepayments		33,715	28,269
Cash and cash equivalents	**17, 18**	616,041	559,543
		1,108,985	**1,060,861**
Total assets		**1,302,570**	**1,179,495**
Equity and liabilities			
Equity			
Share capital	**18**	8,322	8,149
Distributable equity		(171,143)	(113,855)
Total equity		**(162,821)**	**(105,706)**
Non-current liabilities			
Borrowings	**17, 18**	385,254	365,080
Contract liabilities	**15**	1,123	5,000
Deferred tax liabilities	**10**	9,623	7,258
		396,000	**377,338**
Current liabilities			
Convertible notes, matures in April 2028			
Borrowings	**17, 18**	429,391	458,207
Derivative liabilities	**17, 18**	256,231	150,670
		685,622	**608,877**
Other current liabilities			
Borrowings	**17, 18**	57,141	33,329
Contract liabilities	**15**	4,944	936
Trade payables and accrued expenses	**17, 18**	90,657	96,394
Other liabilities		58,204	67,956
Income tax payables		6,427	1,222
Provisions	**16**	166,396	99,149
		383,769	**298,986**
		1,069,391	**907,863**
Total liabilities		**1,465,391**	**1,285,201**
Total equity and liabilities		**1,302,570**	**1,179,495**

Consolidated Statements of Changes in Equity

(EUR'000)	Notes	Share Capital	Distributable Equity: Share Premium	Distributable Equity: Treasury shares	Distributable Equity: Foreign Currency Translation Reserve	Distributable Equity: Accumulated Deficit	Total
Equity as of January 1, 2023		**7,675**	**2,112,863**	**(149)**	**3,452**	**(1,860,493)**	**263,348**
Net profit/(loss) for the year		—	—	—	—	(481,447)	**(481,447)**
Other comprehensive income/(loss), net of tax		—	—	—	(2,731)	—	**(2,731)**
Total comprehensive income/(loss)		**—**	**—**	**—**	**(2,731)**	**(481,447)**	**(484,178)**
Transactions with Owners							
Share-based payment	**8**	—	—	—	—	66,660	**66,660**
Transfer under stock incentive programs		—	—	3	—	(3)	**—**
Net settlement under stock incentive programs		—	—	—	—	(1,812)	**(1,812)**
Capital increase	**18**	74	10,211	—	—	—	**10,285**
Equity as of December 31, 2023		**7,749**	**2,123,074**	**(146)**	**721**	**(2,277,095)**	**(145,697)**
Net profit/(loss) for the year		—	—	—	—	(378,084)	**(378,084)**
Other comprehensive income/(loss), net of tax		—	—	—	1,062	—	**1,062**
Total comprehensive income/(loss)		**—**	**—**	**—**	**1,062**	**(378,084)**	**(377,022)**
Transactions with Owners							
Share-based payment	**8**	—	—	—	—	95,512	**95,512**
Transfer under stock incentive programs	**18**	—	—	33	—	(33)	**—**
Capital increase	**18**	400	340,392	—	—	—	**340,792**
Cost of capital increase		—	(19,291)	—	—	—	**(19,291)**
Equity as of December 31, 2024		**8,149**	**2,444,175**	**(113)**	**1,783**	**(2,559,700)**	**(105,706)**
Net profit/(loss) for the year		—	—	—	—	(228,034)	**(228,034)**
Other comprehensive income/(loss), net of tax		—	—	—	(3,538)	—	**(3,538)**
Total comprehensive income/(loss)		**—**	**—**	**—**	**(3,538)**	**(228,034)**	**(231,572)**
Transactions with Owners							
Share-based payment	**8**	—	—	—	—	116,171	**116,171**
Acquisition of treasury shares	**18**	—	—	(16)	—	(17,380)	**(17,396)**
Transfer under stock incentive programs	**18**	—	—	49	—	(49)	**—**
Net settlement under stock incentive programs		—	—	—	—	(11,396)	**(11,396)**
Capital increase	**18**	173	86,905	—	—	—	**87,078**
Equity as of December 31, 2025		**8,322**	**2,531,080**	**(80)**	**(1,755)**	**(2,700,388)**	**(162,821)**

Consolidated Statement of Cash Flows for the Years Ended December 31

(EUR'000)	Notes	2025	2024	2023
Operating activities				
Net profit/(loss) for the year		**(228,034)**	**(378,084)**	**(481,447)**
Reversal of finance income		(113,999)	(25,609)	(43,857)
Reversal of finance expenses		206,687	100,027	44,065
Reversal of (gain)/loss on disposal of property, plant and equipment		—	(91)	5
Reversal of income taxes		15,383	4,843	7,303
Adjustments for non-cash items:				
Non-cash consideration relating to revenue		(5,630)	(27,069)	(2,354)
Share of (profit)/loss of associates		(16,308)	20,060	18,395
Share-based payment		116,171	95,512	66,660
Depreciation		17,206	17,247	18,428
Impairment of property, plant and equipment		5,283	—	7,834
Amortization		490	467	483
Changes in working capital:				
Inventories		(5,920)	(86,678)	(78,258)
Receivables		15,588	(118,607)	(32,773)
Prepayments		(6,051)	10,392	(11,413)
Contract liabilities		131	(1,197)	(7,080)
Trade payables, accrued expenses and other liabilities		(10,373)	26,965	3,551
Provisions		77,585	61,968	26,187
Cash flows generated from/(used in) operations		**68,209**	**(299,854)**	**(464,271)**
Finance income received		15,302	14,374	17,048
Finance expenses paid		(22,935)	(15,205)	(15,672)
Income taxes received/(paid)		(6,679)	(5,512)	(4,466)
Cash flows from/(used in) operating activities		**53,897**	**(306,197)**	**(467,361)**
Investing activities				
Proceeds from disposal of property, plant and equipment		—	950	51
Acquisition of intangible assets and property, plant and equipment		(8,485)	(1,427)	(2,442)
Settlement of marketable securities		—	7,353	288,865
Cash flows from/(used in) investing activities		**(8,485)**	**6,876**	**286,474**
Financing activities				
Repayment of borrowings		(21,958)	(11,365)	(10,438)
Net proceeds from borrowings	**17**	—	134,158	136,256
Proceeds from exercise of warrants		87,078	30,514	10,286
Proceeds from follow-on public offering		—	309,913	—
Costs of follow-on public offering		—	(19,291)	—
Acquisitions of treasury shares, net of transactions costs		(17,396)	—	—
Payment of withholding taxes under stock incentive programs		(11,396)	—	(1,812)
Cash flows from/(used in) financing activities		**36,328**	**443,929**	**134,292**
Increase/(decrease) in cash and cash equivalents		**81,740**	**144,608**	**(46,595)**
Cash and cash equivalents at January 1		559,543	392,164	444,767
Effect of exchange rate changes on balances held in foreign currencies		(25,242)	22,771	(6,008)
Cash and cash equivalents at December 31		**616,041**	**559,543**	**392,164**

Notes to the Consolidated Financial Statements

Note 1—General Information

Ascendis Pharma A/S, together with its subsidiaries, is a global biopharmaceutical company focused on applying its innovative TransCon technology platform to make a meaningful difference for patients. Ascendis Pharma A/S was incorporated in 2006 and is headquartered in Hellerup, Denmark. Unless the context otherwise requires, references to the "Company," "we," "us," and "our," refer to Ascendis Pharma A/S and its subsidiaries.

The address of the Company's registered office is Tuborg Boulevard 12, DK-2900 Hellerup, Denmark. The Company's registration number in Denmark is 29918791.

On February 2, 2015, the Company completed an initial public offering which resulted in the listing of American Depositary Shares ("ADSs"), representing the Company's ordinary shares, under the symbol "ASND" in the United States on The Nasdaq Global Select Market.

The Company's Board of Directors (or "Board") approved these consolidated financial statements on February 11, 2026.

Note 2—Summary of Material Accounting Policies

Basis of Preparation

The consolidated financial statements are prepared in accordance with the IFRS Accounting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"), and as adopted by the European Union (the "EU").

The accounting policies applied when preparing the consolidated financial statements are described in detail below and are applied for all group entities. Significant accounting judgements and sources of estimation uncertainties used when exercising the accounting policies are described in Note 3, "Significant Accounting Judgements and Estimates."

These consolidated financial statements have been prepared under the historical cost convention, apart from certain financial instruments that are measured at fair value at initial recognition.

New and Amended IFRS Accounting Standards and Interpretations

In August 2023, the IASB amended IAS 21, "The Effects of Changes in Foreign Exchange Rates: Lack of Exchangeability," to help entities determine whether a currency is exchangeable into another currency and which spot exchange rate to use when it is not. These new requirements apply for annual reporting periods beginning on or after January 1, 2025. The Company has assessed this amendment and concluded that this did not have an impact on its operations or financial statements for the year ended December 31, 2025.

No other new and amended standards and interpretations applied for the first time in 2025.

Going Concern

These consolidated financial statements have been prepared on a going concern basis. Management has assessed the Company's ability to continue as a going concern and has concluded that there are no material uncertainties that may cast significant doubt on the Company's ability to continue in operational existence for at least twelve months after the reporting date.

Basis of Consolidation

The consolidated financial statements include the parent company, Ascendis Pharma A/S, and all enterprises over which the parent company has control. Control of an enterprise exists when the Company has exposure, or rights to, variable returns from its involvement with the enterprise and has the ability to control those returns through its power over the enterprise. Accordingly, the consolidated financial statements include Ascendis Pharma A/S and the subsidiaries listed in Note 21, "Investments in Group Enterprises and Associates".

Consolidation Principles

Subsidiaries, which are enterprises the Company controls, are fully consolidated from the date upon which control is transferred to the Company. They are deconsolidated from the date control ceases.

Control over an enterprise is reassessed if facts and circumstances indicate that there are changes to one or more of the three elements of control, respectively:

- the contractual arrangement(s) with the other vote holders of the enterprise;
- the Company's voting rights and potential voting rights; and
- rights arising from other contractual arrangements.

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

Subsidiaries apply accounting policies in line with the Company's accounting policies. When necessary, adjustments are made to bring the entities' accounting policies in line with those of the Company.

Investments in Associates

An associate is an entity over which the Company has significant influence over financial and operational decisions but without having control or joint control. The Company's associates are accounted for using the equity method and initially recognized at cost. Thereafter, the carrying amount of the investment is adjusted to recognize changes in the Company's share of net assets and other comprehensive income of the associates since the acquisition or establishment date. The Company discontinues recognition of further losses when its interest in an associate is reduced to nil, except where the Company has legal or constructive obligations to cover such losses.

Share of profit/(loss) of associates in the consolidated statements of profit or loss include the Company's share of result after tax of the associates after any adjustments made to bring the associates accounting policies in line with those of the Company. Transactions between the associates and the Company are eliminated proportionally according to the Company's interest in the associates. Unrealized gains and losses resulting from transactions between the Company and its associates are eliminated to the extent of the Company's interest in the associates.

When the Company's interest in an associate is reduced but significant influence is retained, the transaction is accounted for as a partial disposal. A gain or loss is recognized in profit or loss for the portion of the investment derecognized including the proportionate share of amounts previously recognized in other comprehensive income that relate to the disposed interest. Any increase in the associate's net assets arising from the issuance of new shares is reflected in share of profit/(loss) of associates. The retained interest continues to be accounted for using the equity method.

On each reporting date, the Company determines whether there are indications that the investment is impaired. If there is such evidence, the amount of impairment is calculated as the difference between the recoverable amount of the associate and its carrying amount. Any impairment loss is recognized in the consolidated statements of profit or loss.

Foreign Currency

Functional and Presentation Currency

Items included in the consolidated financial statements are measured using the functional currency of each group entity. Functional currency is the currency of the primary economic environment in which the entity operates. The consolidated financial statements are presented in Euros (or "EUR"), which is also the functional currency of the parent company.

Translation of Transactions and Balances

On initial recognition, transactions in currencies other than the individual entity's functional currency are translated applying the exchange rate in effect at the date of the transaction. Receivables, payables and other monetary items denominated in foreign currencies that have not been settled at the reporting date are translated using the exchange rate in effect at the reporting date. Monetary items carried at fair value that are denominated in foreign currencies are translated at the rates prevailing at the date when the fair value was determined.

Exchange rate differences that arise between the rate at the transaction date and the rate in effect at the payment date, or the rate at the reporting date, are recognized in profit or loss as finance income or finance expenses. Property, plant and equipment, intangible assets and other non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates as of the dates of the initial transactions.

Currency Translation of Group Enterprises

When subsidiaries or associates present their financial statements in a functional currency other than EUR, their statements of profit or loss are translated at average exchange rates. Balance sheet items are translated using the exchange rates at the reporting date. Exchange rate differences arising from translation of foreign entities' balance sheet items at the beginning of the year to the reporting date exchange rates as well as from translation of statements of profit or loss from average rates to the exchange rates at the reporting date are recognized in other comprehensive income. Similarly, exchange rate differences arising from changes that have been made directly in a foreign subsidiary's equity are recognized in other comprehensive income.

Revenue

Commercial Products

Revenue is recognized when the customer has obtained control of the goods and it is probable that the Company will collect the consideration to which it is entitled for transferring the goods. Control is transferred upon delivery.

Revenue is measured at the contractual sales price, reflecting the consideration received or receivable from customers, net of value added taxes, and provisions for a variety of sales deductions such as prompt pay discounts, shelf stock adjustments and applicable sales deductions attributable to various commercial arrangements, managed healthcare organizations, government programs, and co-pay arrangements. In addition, goods are principally sold on a "sale-or-return" basis, where customers may return products in line with the Company's return policy. Sales deductions and product returns are considered variable consideration and are estimated at the time of sale using the expected value method. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net contractual price only to the extent that it is highly probable that a significant reversal will not occur.

Unsettled sales deductions and product returns are recognized as provisions when timing or amount is uncertain. Payable amounts that are absolute are recognized as other liabilities. Sales discounts and deductions that are payable to customers are offset in trade receivables.

Sales-based royalty and sales-based milestone income promised in exchange for a license of intellectual property, which is interdependent with sale of goods under such license agreements, is recognized as revenue from commercial products upon occurrence of the later of subsequent sale or satisfaction of the performance obligation.

Other Revenue

Other revenue relates to collaboration and license agreements (or "Strategic Collaborations"), where the counterparts are considered customers of the Company. When contracts with these customers are entered into, the goods and/or services promised in the contract are assessed to identify distinct performance obligations. A promise in the agreement is considered a distinct performance obligation if both of the following criteria are met:

- the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct); and
- the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract).

For collaboration and license agreements that contain multiple promises to the customer, the promises are identified and accounted for as separate performance obligations if these are distinct. If promises are not distinct, those goods or services are combined with other promised goods or services until a bundle of goods or services that is distinct is identified.

The transaction price in the contract is measured at fair value and reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Under license agreements, the transaction price may include up-front payments, royalty and milestone payments.

Sales-based royalty and sales-based milestone income promised in exchange for a license of intellectual property is recognized as revenue at the later of the occurrence of subsequent sale or satisfaction of the performance obligation to which some or all of the royalty or milestone has been allocated. Milestone income related to regulatory activities is included in the transaction price at the point in time that it is highly probable that the applicable milestone criteria is met.

The transaction price is allocated to each performance obligation according to their stand-alone selling prices and is recognized when control of the goods or services is transferred to the customer, either over time or at a point in time, depending on the specific terms and conditions in the contracts. License agreements, which transfer rights to the Company's intellectual property ("IP"), are classified as "right-to-access", with revenue recognized over time, or as "right-to-use" with revenue recognized at a point in time, depending on the specific terms and conditions in the agreements.

Sale of clinical trial supply is recognized as revenue when the customer has obtained control of the goods and it is probable that the Company will collect the consideration to which it is entitled for transferring the goods. Control is transferred upon delivery. Rendering of services is recognized as revenue over the service period as stipulated under the applicable agreement.

Research and Development Expenses

Research and development expenses consist primarily of manufacturing costs, preclinical and clinical study costs and costs for process optimizations and improvements performed by Clinical Research Organizations ("CROs") and Contract Manufacturing Organizations ("CMOs"), salaries and other personnel costs including pension and share-based payment, the cost of facilities, professional fees, cost of obtaining and maintaining the Company's intellectual property portfolio, and depreciation of non-current assets related to research and development activities.

Research costs are incurred at the early stages of the drug development cycle from the initial drug discovery and include a variety of preclinical research activities in order to assess potential drug candidates in non-human subjects, prior to filing an Investigational New Drug Application ("IND"), or equivalent. Research costs are recognized in the consolidated statement of profit or loss when incurred.

Development activities relate to activities following an IND, or equivalent, and typically involve a single product candidate undergoing a series of studies to illustrate its safety profile and effect on human beings, prior to obtaining the necessary approval from the appropriate authorities. Development activities comprise drug candidates undergoing clinical trials starting in Phase I (first time drug is administered in a small group of humans), and further into Phase II and III, which include administration of drugs in larger patient groups. Following, and depending on clinical trial results, a Biologic License Application ("BLA") or New Drug Application ("NDA") may be submitted to the authorities, to apply for marketing approval, which, with a positive outcome will permit the Company to market and sell the products. Long-term extension trials may be ongoing following submission of a BLA or NDA.

Development costs also include product development and pre-commercial manufacturing costs related to development product candidates, and write-downs of inventories manufactured for late-stage development product candidates prior to marketing approval being obtained (pre-launch inventories) and any reversal of such write-downs.

Due to the risk related to the development of pharmaceutical products, the Company cannot estimate the future economic benefits associated with individual development activities with sufficient certainty until the development activities have been finalized and the necessary market approval of the final product has been obtained. As a consequence, all development costs are recognized in the consolidated statement of profit or loss when incurred.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses comprise salaries and other personnel costs including pension and share-based payment, office supplies, cost of facilities, professional fees, and depreciation of non-current assets related to selling, general and administrative activities, including pre-commercial and commercial activities. Selling, general, and administrative expenses are recognized in the consolidated statement of profit or loss when incurred.

Share-based Incentive Programs

Share-based incentive programs comprise warrant programs, Restricted Stock Unit programs ("RSU-programs") and Performance Stock Unit Programs ("PSU-programs") which are classified as equity-settled share-based payment transactions.

The cost of equity-settled transactions is determined by the fair value at the date of grant. For warrant programs, the fair value of each warrant granted is determined using the Black-Scholes option-pricing model. For RSU-programs and PSU-programs, the fair value of each RSU or PSU granted is equal to the closing share price on the date of grant of the underlying ADS. Any social security contributions payable in connection with the grant or exercise of the warrants are recognized as expenses when incurred. The assumptions used for estimating the fair value of share-based payment transactions are disclosed in Note 8, "Share-based Payment."

The cost is recognized together with a corresponding increase in equity over the period in which the performance and/or service conditions are fulfilled (i.e., the vesting period). The fair value determined at the grant date of the equity-settled share-based payment is expensed on a straight-line basis over the vesting period for each tranche, based on the best estimate of the number of equity instruments that will ultimately vest. No expense is recognized for grants that do not ultimately vest.

Where an equity-settled grant is cancelled other than upon forfeiture when vesting conditions are not satisfied, the grant is treated as if it vested on the date of the cancellation, and any expense not yet recognized for the grant is recognized immediately.

Where the terms and conditions for an equity-settled grant are modified, the services measured at the grant date fair value over the vesting period are recognized, subject to performance and/or service conditions that were specified at the initial grant date(s). Additionally, at the date of modification, unvested grants are re-measured and any increase in the total fair value is recognized over the vesting period. If a new grant is substituted for the cancelled grant and designated as a replacement grant on the date that it is granted, the cancelled and new grants are treated as if they were a modification of the original grant.

Finance Income and Expenses

Finance income and expenses comprise interest income and expenses, realized and unrealized exchange rate gains and losses on transactions denominated in foreign currencies, fair value remeasurement gains and losses on derivative liabilities, and remeasurement gains and losses on royalty funding liabilities.

Interest income and interest expenses are stated on an accrual basis using the principal and the effective interest rate. The effective interest rate is the discount rate that is used to discount expected future cash payments or receipts through the expected life of the financial asset or financial liability to the amortized cost (the carrying amount) of such asset or liability.

Income Taxes

Tax for the year, which consists of current tax for the year and changes in deferred tax, is recognized in the consolidated statement of profit or loss by the portion attributable to the profit or loss for the year and recognized directly in equity or other comprehensive income by the portion attributable to entries directly in equity and in other comprehensive income. The current tax payable or receivable is recognized in the consolidated statement of financial position, stated as tax computed on this year's taxable income, adjusted for prepaid tax.

When computing the current tax for the year, the tax rates and tax rules enacted or substantially enacted at the reporting date are used. Current tax payable is based on taxable profit or loss for the year. Taxable profit or loss differs from net profit or loss as reported in the consolidated statements of profit or loss because it excludes items of income or expense that are taxable or deductible in prior or future years. In addition, taxable profit or loss excludes items that are never taxable or deductible.

Deferred tax is recognized according to the balance sheet liability method of all temporary differences between carrying amounts and tax-based values of assets and liabilities, apart from deferred tax on all temporary differences occurring on initial recognition of goodwill or on initial recognition of a transaction which is not a business combination, and for which the temporary difference found at the time of initial recognition neither affects profit or loss nor taxable income.

Deferred tax liabilities are recognized on all temporary differences related to investments in subsidiaries and/or associates, unless the Company is able to control when the deferred tax is realized, and it is probable that the deferred tax will not become due and payable as current tax in the foreseeable future.

Deferred tax assets, including the tax base of tax loss carry forwards, are recognized in the statement of financial position at their estimated realizable value, either as a set-off against deferred tax liabilities or as net tax assets for offset against future positive taxable income. Deferred tax assets are only offset against deferred tax liabilities if the entity has a legally enforceable right to offset, and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same tax jurisdiction. Deferred tax is calculated based on the planned use of each asset and the settlement of each liability, respectively.

Deferred tax is measured using the tax rates and tax rules in the relevant countries that, based on acts in force or acts in reality in force at the reporting date are expected to apply when the deferred tax is expected to crystallize as current tax. Changes in deferred tax resulting from changed tax rates or tax rules are recognized in the consolidated statement of profit or loss unless the deferred tax is attributable to transactions previously recognized directly in equity or other comprehensive income. In the latter case, such changes are also recognized in equity or other comprehensive income. On every reporting date, it is assessed whether sufficient taxable income is likely to arise in the future for the deferred tax asset to be utilized.

Intangible assets

Goodwill

Goodwill acquired in a business combination is initially measured at cost, being the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests over the net identifiable assets acquired and liabilities assumed.

After initial recognition, goodwill is measured at cost less any accumulated impairment losses. Goodwill is not amortized but is subject to impairment testing at least on a yearly basis. For the purpose of impairment testing, goodwill acquired in a business combination is allocated to each of the cash-generating units, or group of cash-generating units, that are expected to benefit from the synergies of the combination. Each cash-generating unit or group of cash-generating units to which goodwill is allocated represents the lowest level within the Company at which the goodwill is monitored for internal management purposes.

Software

Software assets comprise administrative applications and serve general purposes to support the Company's operations.

Development costs that are directly attributable to the design, customization, implementation, and testing of identifiable and unique software assets controlled by the Company are recognized as intangible assets from the time that; (1) the software asset is clearly defined and identifiable; (2) technological feasibility, adequate resources to complete, and an internal use of the software asset can be demonstrated; (3) the expenditure attributable to the software asset can be measured reliably; and (4) the Company has the intention to use the software asset internally. The Company does not capitalize software with no alternative use, or where economic benefit depends on marketing approvals of drug candidates and where marketing approvals have not been obtained.

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses. Amortization of the asset begins when the development is complete, and the asset is available for use.

Software assets are amortized over the period of expected future benefits. Amortization is recognized in research and development expenses, and selling, general and administrative expenses, as appropriate. Expenditures that do not meet the criteria above are recognized as an expense as incurred.

Property, Plant and Equipment

Property, plant and equipment primarily comprises leasehold improvements, office facilities, and process equipment and tools which are located at CMOs. Property, plant and equipment also includes right-of-use assets. Refer to the separate section "Leases."

Property, plant and equipment is measured at cost less accumulated depreciation and impairment losses. Cost comprises the acquisition price, costs directly attributable to the acquisition and preparation costs of the asset until the time when it is ready to be used in operation. Subsequent costs are included in the carrying amount of the asset or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the assets will flow to the Company and costs of the items can be measured reliably. All repair and maintenance costs are charged to the consolidated statement of profit or loss during the financial periods in which they are incurred.

Plant and equipment acquired for research and development activities with alternative use, which is expected to be used for more than one year, is capitalized and depreciated over the estimated useful life as research and development expenses. Plant and equipment acquired for research and development activities, which has no alternative use, is recognized as research and development expenses when incurred.

If the acquisition or use of the asset involves an obligation to incur costs of decommissioning or restoration of the asset, the estimated related costs are recognized as a provision and as part of the relevant asset's cost, respectively.

The basis for depreciation is cost less estimated residual value. The residual value is the estimated amount that would be earned if selling the asset today net of selling costs, assuming that the asset is of an age and a condition that is expected after the end of its useful life. Cost of a combined asset is divided into smaller components, with such significant components depreciated individually if their useful lives vary. Depreciation commences when the asset is available for use, which is when it is in the location and condition necessary for it to be capable of operating in the manner intended.

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

Process plant and machinery	5 - 10 years
Other equipment	3 - 5 years
Leasehold improvements	3 - 15 years
Right-of-use assets	2 - 15 years

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

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

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

Impairment of Non-current Assets

The recoverable amount of goodwill is estimated annually irrespective of any recorded indications of impairment. Property, plant and equipment and finite-lived intangible assets are reviewed for impairment whenever events or circumstances indicate that the carrying amount may not be recoverable.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use.

For the purpose of assessing impairment, assets are grouped at the lowest levels for which there are largely independent cash inflows, or cash-generating units, which for goodwill represent the lowest level within the enterprise at which the goodwill is monitored for internal management purposes. Prior impairments of non-current assets, other than goodwill, are reviewed for possible reversal at each reporting date.

Inventories

Inventories comprise raw materials, work in progress and finished goods. The cost of work in progress and finished goods comprise service expenses incurred at CMOs, raw materials consumed, incremental storage and transportation, other direct materials, and a proportion of manufacturing overheads based on normal operation capacity.

Inventories are measured at the lower of cost incurred in bringing it to its present location and condition, and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale. Cost is measured using the first-in, first-out method. Work in progress and finished goods are measured under a standard cost method that takes into account normal levels of consumption, yields, labor, efficiency and capacity utilization. Production processes are complex, where actual yields and consumptions are sensitive to a wide variety of manufacturing conditions. Standard cost variances are reviewed regularly and adjusted to ensure inventories approximate actual cost of production.

If net realizable value is lower than cost, a write-down is recognized as the excess amount by which cost exceeds net realizable value, as part of cost of sales, or selling, general, and administrative expenses, as appropriate. The amount of reversal of write-down of inventories arising from an increase in net realizable value is recognized as a reduction in the same profit or loss line item as the original write-down was recognized, in the period in which the reversal occurs.

Manufacturing of pre-launch inventories is initiated for late-stage product candidates where manufacturing costs are recognized as inventories. However, since pre-launch inventories are not realizable prior to obtaining marketing approval, pre-launch inventories are immediately written down to zero through research and development expenses. If marketing approval is obtained, prior write-downs of pre-launch inventories are reversed through research and development expenses.

Cost of inventories is recognized as part of cost of sales in the period in which the related revenue is recognized.

Receivables

Receivables comprise trade receivables, lease receivables, income tax receivables and other receivables.

Trade receivables are classified as financial assets at amortized cost, as these are held to collect contractual cash flows and thus give rise to cash flows representing solely payments of principal and interest. Trade receivables are initially recognized at their transaction price and subsequently measured at amortized cost.

Where the Company acts as an intermediate lessor and a sublease is classified as a finance lease, the Company recognize a net investment in the lease (lease receivable) and derecognize the portion of the asset that is subject to the sublease. The lease receivable is initially measured at the present value of lease payments receivable plus any unguaranteed residual value. Any difference on derecognition of the right-of-use asset is recognized in the consolidated statement of profit or loss. Subsequently, finance income is recognized using the effective interest method. Further the lease receivable is reduced by lease payments received.

Income tax receivables, and other receivables related to deposits, VAT and other indirect taxes are measured at cost less impairment. Carrying amounts of receivables usually equals their nominal value less provision for impairments.

Prepayments

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

Marketable Securities

Marketable securities may comprise government bonds, treasury bills, commercial papers, and other securities traded on established markets.

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

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

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

Cash and Cash Equivalents

Cash and cash equivalents comprise cash and on-demand deposits with financial institutions, and highly liquid marketable securities with a maturity of three months or less after the date of acquisition (trade-date). Cash and cash equivalents are measured at amortized cost.

Allowance for Expected Credit Losses on Financial Assets

Financial assets comprise receivables (excluding receivables relating to VAT, other indirect tax and income tax), marketable securities, and cash and cash equivalents. Impairment of financial assets is determined on the basis of a forward-looking Expected Credit Loss ("ECL") model. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and the cash flows expected to be received, discounted by an approximation of the original effective interest rate.

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

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

Shareholders' Equity

The share capital comprises the nominal amount of the parent company's ordinary shares, each at a nominal value of DKK 1, or approximately €0.13. All shares are fully paid.

Share premium comprises the amounts received, attributable to shareholders' equity, in excess of the nominal amount of the shares issued at the parent company's capital increases, reduced by any expenses directly attributable to the capital increases. Under Danish legislation, share premium is an unrestricted reserve that is available to be distributed as dividends to a company's shareholders. Also, under Danish legislation, the share premium reserve can be used to offset accumulated deficits.

Treasury shares reserve comprise nominal amounts of holding of own equity instruments. No gain or loss is recognized in profit or loss on the purchase, sale, transfer or cancellation of the Company's own equity instruments. The treasury shares reserve is part of unrestricted reserves and accordingly, reduce the amount available to be distributed as dividends to the Company's shareholders.

Foreign currency translation reserve includes exchange rate adjustments relating to the translation of the results and net assets of foreign operations from their functional currencies to the presentation currency.

The accumulated reserve of a foreign operation is reclassified to the consolidated statement of profit or loss at the time the Company loses control, and thus cease to consolidate such foreign operation. The foreign currency translation reserve is an unrestricted reserve that is available to be distributed as dividends to the Company's shareholders.

Retained earnings/(accumulated deficit) represents the accumulated profits or losses from the Company's operations, including corresponding entries to share-based payments recognized in the consolidated statement of profit or loss. In addition, premiums from acquisition and sale of treasury shares are recognized as part of this reserve. A positive reserve is available to be distributed as dividends to the Company's shareholders.

Convertible Senior Notes and Embedded Derivative Liabilities

Convertible senior notes ("convertible notes") are separated into a financial liability and an embedded derivative component based on the terms and conditions of the contract. The embedded derivative component is accounted for separately if it is not deemed closely related to the financial liability.

The convertible notes include an embedded equity conversion option which is not deemed closely related to the financial liability, and initially recognized and measured separately at fair value as derivative liabilities based on the stated terms upon issuance of the convertible notes. The conversion option is classified as a foreign currency conversion option and thus not convertible into a fixed number of shares for a fixed amount of cash. Accordingly, the conversion option is subsequently recognized and measured as a derivative liability at fair value through profit or loss, with any subsequent remeasurement gains or losses recognized as part of finance income or expenses.

In addition, the convertible notes include a redemption option, which entitle the Company to redeem the notes at a cash amount equal to the principal amount of the convertible notes, plus accrued and unpaid interest. The redemption option is closely related to the financial liability, and not separately accounted for. The initial carrying amount of the financial liability component including the redemption option is the residual amount of the proceeds, net of transaction costs, after separating the derivative component.

Transaction costs are apportioned between the financial liability and derivative component based on the allocation of proceeds when the instrument is initially recognized. Transaction costs apportioned to the financial liability component form part of the effective interest and are amortized over the expected lifetime of the liability. Transaction costs allocated to the derivative component are expensed as incurred.

The financial liability is subsequently measured at amortized cost until it is extinguished on conversion, upon optional redemption or repayment at maturity. Convertible notes are presented as borrowings, together with the derivative liabilities on the statement of financial position, separately under current liabilities as "Convertible notes, matures in April 2028."

Royalty Funding Liabilities

Royalty funding liabilities relate to the Company's contractual obligations to pay a predetermined percentage of future revenue from sale of commercial products until reaching a predetermined multiple of proceeds received, pursuant to the detailed provisions of the capped synthetic royalty funding agreements.

Where relevant, royalty funding liabilities are separated into a financial liability and embedded derivative components based on the terms and conditions of the applicable royalty funding agreement. Embedded derivative components are accounted for separately, unless these are deemed closely related to the financial liability. The royalty funding agreements include a buy-out option where the value is dependent on non-financial variables that are specific to the Company. Accordingly, the buy-out option is not accounted for separately as a derivative.

The financial liability is recognized when the Company becomes party to the contractual provisions of the royalty funding agreement and measured at amortized cost until it is extinguished upon exercising a buy-out option or upon achieving the predetermined multiple of proceeds received.

The effective interest rate is estimated at initial recognition and takes into account incremental transaction costs and anticipated amount and timing of future cash flows, which further depends on future commercial revenue forecasts and the probability of exercising the buy-out option. The amortized cost is remeasured prospectively when there is a material change in expectations to amount and timing of future cash flows, which will increase or decrease future interest expenses. Remeasurement gain or losses are recognized through the profit or loss as finance income or expenses, respectively.

Royalty funding liabilities that are classified as a financial liability are presented as part of borrowings in the statement of financial position.

Leases

Right-of-use Assets

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

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

Lease Liabilities

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

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

Lease liabilities are presented as part of borrowings in the statement of financial position.

Short-term Leases and Leases of Low-value Assets

Expenses related to short-term leases (12 months or less) and leases of low-value assets are recognized on a straight-line basis through profit or loss.

Provisions

Provisions comprise unsettled sales deductions and product returns regarding revenue from sale of commercial products where amount or timing of payment is uncertain.

Provisions for sales deductions attributed to various commercial arrangements, managed healthcare organizations, government programs, and co-pay arrangements are recognized when the related sales takes place and measured using the expected value method. Payable amounts for managed healthcare organizations and government programs are generally settled within 180 days from the transaction date.

Provisions for estimated product returns are measured according to the contractual sales price based on expected product returns.

Trade Payables and Accrued Expenses

Trade payables and accrued expenses are measured at amortized cost.

Other Liabilities

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

Contract Liabilities

Contract liabilities comprise deferred income from collaboration and license agreements, where consideration received does not match the individual deliverables with respect to amount and satisfied performance obligations.

Contract liabilities are measured at the fair value of the consideration received and is recognized as revenue in the consolidated statement of profit or loss when the relevant performance obligation, to which the deferred income relates, is satisfied.

Statement of Cash Flows

The statement of cash flows shows cash flows from operating, investing and financing activities as well as cash and cash equivalents at the beginning and the end of the financial year.

Cash flows from operating activities are presented using the indirect method and calculated as the profit or loss adjusted for non-cash items, working capital changes as well as finance income, finance expenses and income taxes paid.

Cash flows from investing activities include payments in connection with acquisition, development, improvement and sale, etc., of property, plant and equipment, investments in associates and marketable securities.

Cash flows from financing activities comprise payments related to the capital structure of the Company, including changes in the share capital and treasury shares, and issuance and repayments under the Company's borrowing activities.

The effect of exchange rate changes on cash and cash equivalents held or due in a foreign currency is presented separately from cash flows from operating, investing and financing activities. Cash flows in currencies other than the functional currency are recognized in the statement of cash flows, using the average exchange rates.

Cash and cash equivalents comprise cash and on-demand bank deposits with financial institutions and highly liquid marketable securities with a maturity of three months or less after the date of acquisition.

Basic Earnings per Share

Basic Earnings per Share ("EPS") is calculated as the consolidated net income or loss from continuing operations for the period divided by the weighted average number of ordinary shares outstanding adjusted for the weighted average number of treasury shares during the year.

Diluted Earnings per Share

Diluted EPS is calculated as the consolidated net income or loss from continuing operations for the period divided by the weighted average number of ordinary shares outstanding adjusted for the weighted average number of treasury shares during the year, and the dilutive effect of outstanding warrants, RSUs, PSUs, and convertible notes, if any.

New IFRS Accounting Standards Not Yet Effective

The IASB has issued a number of new or amended standards, which have not yet become effective or have not yet been adopted by the EU. Therefore, these new standards have not been incorporated in these consolidated financial statements.

IFRS 18, "Presentation and Disclosure in Financial Statements"

In April 2024, the IASB issued IFRS 18, "Presentation and Disclosure in Financial Statements" ("IFRS 18"), which replaces IAS 1, "Presentation in Financial Statements." IFRS 18 introduces new categories and subtotals in the statement of profit or loss, into:

- Operating activities;
- Investing activities;
- Financing activities;
- Income taxes; and
- Discontinued operations.

In addition, IFRS 18 includes new requirements for the location, aggregation and disaggregation of financial information, and disclosure of management-defined performance measures, as defined, if any. IFRS 18 does not include any measurement changes.

If approved by the EU, the amendments will be effective for annual reporting periods beginning on or after January 1, 2027, and must be applied retrospectively, with early adoption permitted. While IFRS 18 will change the structure and subtotal in the statement of profit or loss, the full impact from implementing IFRS 18 is currently being analyzed.

The consolidated financial statements are not expected to be affected by other new or amended standards.

Note 3 – Significant Accounting Judgements and Estimates

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

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized prospectively.

While the application of critical accounting estimates is subject to material estimation uncertainties, management's ongoing revisions of critical accounting estimates and underlying assumptions have not revealed any material impact to any of the years presented in these consolidated financial statements compared to December 31, 2024.

Significant accounting judgements which have a significant impact on the consolidated financial statements, and key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that have a risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Revenue and Provisions

Provisions for Sales Deductions and Product Returns

Sales deductions and product returns are considered variable consideration and constrained to the extent that a significant reversal in the amount of recognized revenue will not occur when the uncertainties associated with the rebate or chargeback item are subsequently resolved, or for product returns, when the products are distributed to patients.

Provisions for unsettled sales deductions and product returns are estimated on the basis of a percentage of sales as defined by individual agreements and contracts, and for government rebates by individual state- and plan agreements. Further inputs to the calculations are based on payer channel mix, current contract prices under eligible programs and current inventory levels in the distribution channels. Inputs to the calculations are subject to estimation and assumptions and are based on historical experience and other factors that are relevant, and which are available at the reporting date. Provisions are adjusted to absolute amounts and recognized as other liabilities when estimated sales deductions are processed.

As of December 31, 2025, provisions for sales deductions and product returns were €166.4 million compared to €99.1 million, as of December 31, 2024. The development in total provisions is disclosed in Note 16, "Provisions." Due to the nature of these provisions, it is not practicable to give meaningful sensitivity estimates due to the large volume of variables that contribute to the overall rebates, chargebacks, product returns and other sales deductions. Provisions are reviewed and adjusted regularly considering contractual terms, regulatory obligations, payer trends, historical experiences and market projections.

Share-based Payment

Warrant Compensation Costs

IFRS 2, "Share-Based Payment" requires an entity to reflect in its consolidated statement of profit or loss and financial position, the effects of share-based payment transactions. Warrant compensation costs are recognized as cost of sales, research and development expenses or selling, general and administrative expenses, as appropriate, over the vesting period, based on management's best estimate of the number of warrants that will ultimately vest, which is subject to uncertainty.

Warrant compensation costs are measured according to the grant date fair value of the warrants granted. Estimating fair values requires the Company to apply generally accepted valuation models and apply these models consistently according to the terms and conditions of the specific warrant program. Under all warrant programs, the Black-Scholes option-pricing model has been applied to determine the fair value of warrants granted. Subjective judgements and assumptions, which are subject to estimation uncertainties, need to be exercised in determining the appropriate input to the valuation model. These inputs include expected volatility of the Company's share price for a historic period equaling the expected lifetime of the warrants, reflecting the assumption that the historical volatility over a period similar to the life of the warrants is indicative of future trends, expected forfeitures and expected lifetime of warrants.

Warrant compensation cost recognized in the consolidated statement of profit or loss was €23.0 million, €19.7 million and €28.8 million for the years ended December 31, 2025, 2024 and 2023, respectively. Changes to inputs applied to the Black-Scholes option-pricing model could affect the warrant compensation cost. Refer to Note 8, "Share-based Payment," for additional details.

Valuation of Embedded Derivatives

Foreign currency conversion options embedded in the convertible notes are accounted for separately as derivative liabilities at fair value through profit or loss.

Fair value cannot be measured based on quoted prices in active markets, or other observable input, and accordingly, derivative liabilities are measured by use of valuation techniques in the form of the Black-Scholes option-pricing model. Subjective judgements and assumptions, which are subject to estimation uncertainties, need to be exercised in determining the appropriate unobservable input to the valuation model (Level 3 in the fair value hierarchy). This includes volatility of the Company's share price for a historic period, reflecting the assumption that the historical volatility is indicative of a period similar to the expected lifetime of the options.

As of December 31, 2025, the valuation of the derivative liabilities was €256.2 million compared to €150.7 million as of December 31, 2024. Changes in assumptions relating to these factors could affect the reported fair value of derivative liabilities. Refer to Note 17, "Financial Assets and Liabilities," for additional details.

Measurement of Royalty Funding Liabilities

The carrying amount of royalty funding liabilities is measured according to anticipated future cash flows, which further depends on the amount and timing of future revenue from sale of commercial products. Assumptions that impact the amount and timing of future sale of commercial products are subject to estimation uncertainties, and are subject to a number of factors which are not within the Company's control.

As of December 31, 2025, the carrying amount of the royalty funding liabilities was €290.9 million compared to €305.4 million as of December 31, 2024. The Company will periodically revisit the anticipated amount and timing of future sale of commercial products and to the extent such amount or timing is materially different from the previous estimates, a remeasurement gain or loss is recognized through the profit or loss as finance income or expenses, as appropriate, which would further increase or decrease future interest expenses. Refer to Note 17, "Financial Assets and Liabilities" for additional details.

Note 4—Revenue

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

(EUR'000)	2025	2024	2023
Revenue			
Commercial products	683,572	225,728	178,663
Services and clinical supply	18,008	15,570	21,978
Licenses	5,630	122,343	66,077
Milestones	12,922	—	—
Total revenue	**720,132**	**363,641**	**266,718**
Specified per geographical area			
United States [1]	546,388	233,115	191,677
Europe [2]	120,946	123,336	869
Rest of world [1]	52,798	7,190	74,172
Total revenue	**720,132**	**363,641**	**266,718**

(1) From 2025, revenue related to the United States has been disclosed separately. Comparatives for the United States and Rest of World have been restated for comparative purposes.

(2) For the years ended December 31, 2025 and December 31, 2024, Denmark, the country of domicile, contributed with €12.9 million and €95.4 million of revenue, respectively. For the year ended December 31, 2023, no revenue was attributable to Denmark.

Commercial Products

Revenue from sale of commercial products were as follows:

(EUR'000)	2025	2024	2023
Revenue from commercial products			
YORVIPATH®	477,412	28,727	—
SKYTROFA®	206,160	197,001	178,663
Total revenue from commercial products	**683,572**	**225,728**	**178,663**

In the U.S., the Company has established an integrated organization to commercialize the Company's approved Endocrinology Rare Disease products, YORVIPATH® and SKYTROFA®. In Europe, the Company has established its presence by building integrated organizations in select countries ("Europe Direct"), where the Company has launched YORVIPATH and SKYTROFA. Beyond the U.S. and Europe Direct, YORVIPATH and SKYTROFA may also be sold through exclusive sales and distribution agreements with geographic market leaders ("International Markets") and under Strategic Collaborations.

YORVIPATH and SKYTROFA is approved by the U.S. Food and Drug Administration ("FDA") and authorized by the European Commission ("EC") and other regulatory agencies. The Company began selling YORVIPATH in

Europe in the first quarter of 2024 and in the U.S. in December 2024. The Company began selling SKYTROFA in the U.S. in the fourth quarter of 2021 and in Europe in the third quarter of 2023.

For the year ended December 31, 2025, two and for the years ended December 31, 2024 and 2023, four commercial customers represented more than 10% of revenue from commercial products.

Other Revenue

Other revenue is attributable to the Company's Strategic Collaborations, and relates to Novo Nordisk A/S ("Novo Nordisk"), Eyconis, Inc. ("Eyconis"), Teijin Limited ("Teijin") and VISEN Pharmaceuticals ("VISEN").

Novo Nordisk

In November 2024, the Company entered into a research and development collaboration and license agreement (the "Novo Nordisk Agreement") with Novo Nordisk pursuant to which the Company granted Novo Nordisk an exclusive worldwide license to the TransCon technology platform to develop, manufacture and commercialize Novo Nordisk proprietary products (including Semaglutide) in metabolic diseases (including obesity and type 2 diabetes) and a product-by-product exclusive license in cardiovascular diseases (the "IP").

The Novo Nordisk Agreement includes provisions requiring at least one TransCon Semaglutide product and at least one other TransCon technology-based product to be identified, developed and commercialized in metabolic diseases to maintain certain exclusivities in the field, with additional provisions for cardiovascular diseases. Under the terms of the Novo Nordisk Agreement, Novo Nordisk also receives exclusive rights to expand any resulting metabolic disease products into other therapeutic areas. The lead program in the collaboration is a once-monthly TransCon Semaglutide product candidate that will initially target obesity and type 2 diabetes.

Under the Novo Nordisk Agreement, the Company has the potential to receive total payments of up to $285 million in upfront, development and regulatory milestone payments for the lead program. In addition, the Company has the potential to receive sales-based milestone payments and tiered royalties on global net sales. The $285 million includes an upfront fee of $100 million for the exclusive license. For each additional metabolic or cardiovascular disease product candidate, the Company will be eligible to receive payments of up to $77.5 million in development and regulatory milestone payments. In addition, the Company has the potential to receive sales-based milestone payments and tiered royalties on global net sales. Novo Nordisk agreed to pay royalties for each potential licensed product developed under the agreement that are an escalating tiered, mid-single digit percentage of the annual net sales of such licensed product and are subject to reduction due to patent valid claim expiration, biosimilar product market share, payment made under certain licenses for third party intellectual property and Inflation Reduction Act price negotiations.

Under the Novo Nordisk Agreement, the Company agreed to conduct certain pre-agreed early research and development of TransCon product candidates under the collaboration and is eligible to receive cost reimbursement from Novo Nordisk for its performance of such research and development activities under the Novo Nordisk Agreement with respect to such TransCon product candidates. Novo Nordisk is responsible for any other non-clinical and clinical development, regulatory, commercial manufacturing, and commercialization of such TransCon product candidates, and all costs associated with such activities.

Subject to the terms of the Novo Nordisk Agreement, the Company granted Novo Nordisk an exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses, to use its proprietary TransCon technology platform to develop, manufacture and commercialize Novo Nordisk proprietary products in metabolic diseases (including obesity and type 2 diabetes) and a product-by-product exclusive license in cardiovascular diseases. Additionally, the Company granted Novo Nordisk an exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses, to use its proprietary TransCon technology platform to develop, manufacture and commercialize GLP-1 receptor products using the TransCon technology for all indications, except for (i) certain pre-agreed rare endocrine indications, (ii) all indications in respect of the eye and adnexa and (iii) all indications in respect of oncology.

Unless earlier terminated, the Novo Nordisk Agreement has a royalty term that continues, on a per licensed product and per country basis, until the later of (i) the expiration of the last valid patent claim for any of our patents, joint improvement patents, licensed product patents as well as any improvements made by Novo Nordisk covering the licensed product's dosage regimen or target product profile, or (ii) 11 years after the first commercial sale of such licensed product in such country.

The IP comprises the patent protected TransCon technology platform, where future activities do not affect its existing stand-alone functionalities. Accordingly, the IP is classified as "right-to-use" licenses, with revenue recognized at a point in time, where the licensee is granted access to the IP. For the year ended December 31, 2024, "Licenses" includes revenue of €95.3 million related to the upfront payment, which is allocated to transfer of the Company's intellectual property.

Eyconis

In January 2024, the Company announced the formation and launch with Frazier Life Sciences of Eyconis, a separate company created to develop, manufacture, and commercialize TransCon ophthalmology assets globally, together with a $150 million commitment from an investor syndicate that includes Frazier, RA Capital Management, venBio, and HealthQuest Capital.

The Company has granted Eyconis exclusive rights to develop and commercialize TransCon ophthalmology products globally (the "Eyconis Agreement") and received, as consideration, an equity position in the newly formed company. In addition, the Company is eligible to receive development, regulatory, and sales milestone payments, plus single digit royalties on global net sales of commercialized products, if any.

The Company is expected to provide various research and development services, which are subject to separate remuneration, and which will be recognized as revenue over time as rendering of services or reimbursement revenue, as applicable.

For the year ended December 31, 2024, "Licenses" includes revenue of €27.1 million related to the non-cash upfront payment through an equity position in Eyconis, adjusted for internal profit, which is allocated to transfer of the Company's intellectual property (the "IP"). The internal profit relates to the Company's share of the non-cash upfront payment which is recognized as part of "Investments in associates" and recognized as revenue from "Licenses" as the IP is amortized in the associate.

Teijin

In November 2023, the Company entered into an exclusive license agreement (the "Teijin Agreement") with Teijin for the further development and commercialization of TransCon hGH, TransCon PTH, and TransCon CNP for endocrinology rare disease (the "Licensed Products") in Japan. Under the terms of the Teijin Agreement, the Company received an upfront payment of $70 million, with additional development and regulatory milestones of up to $175 million and commercial milestones. In addition, the Company is eligible to receive royalties on net sales of the Licensed Products in Japan, of up to mid-20's percent.

Further, the Company will provide clinical and commercial supply, and development services for joint activities, which are subject to separate remuneration, and which will be recognized as revenue over time as rendering of services or reimbursement revenue, as applicable.

The Licensed Products (the "IP") are patent protected, where future activities do not affect their existing stand-alone functionalities. Accordingly, all three licenses are classified as "right-to-use" licenses, with revenue recognized at a point in time, where the licensee is granted access to the IP. For the year ended December 31, 2023, "Licenses" includes revenue of €63.7 million related to the upfront payment, which is allocated to transfer of the Company's IP. In Japan, YORVIPATH has been commercially available for prescription since November 6, 2025, through Teijin.

VISEN

In November 2018, the Company entered into three exclusive license agreements with VISEN, and includes rendering of services, sale of clinical supply and commercial products.

Note 5—Earnings Per Share

The following table reflects the earnings and share data used in the basic and diluted earnings per share calculations:

(EUR'000, except per share data)	2025	2024	2023
Earnings			
Net profit/(loss) for the year	**(228,034)**	**(378,084)**	**(481,447)**
Number of shares			
Weighted average number of ordinary shares for the purposes of basic and diluted earnings per share	**60,607,131**	**57,891,570**	**56,287,060**
Basic earnings per share	**€(3.76)**	**€(6.53)**	**€(8.55)**
Diluted earnings per share [1]	**€(3.76)**	**€(6.53)**	**€(8.55)**

(1) For the years ended December 31, 2025, December 31, 2024 and December 31, 2023, outstanding warrants, restricted stock units and performance stock units can potentially dilute earnings per share in the future but have not been included in the calculation of diluted earnings per share because they are antidilutive for the years presented. Similarly, 575,000 convertible senior notes which can potentially be converted into 3,456,785 ordinary shares, can potentially dilute earnings per share in the future but have not been included in the calculation of diluted earnings per share because they are antidilutive for the years presented. Refer to Note 8 "Share-based Payment" and Note 17, "Financial Assets and Liabilities," for further information about the share-based incentive programs and convertible notes, respectively.

Note 6—Segment Information

The Company is managed and operated as one business unit. Accordingly, no additional information on business segments or geographical areas is disclosed apart from revenue on geographical areas as disclosed in Note 4, "Revenue." Revenue is specified on geographical areas according to the location of the customer.

The Company's non-current segment assets, which comprise intangible assets, and property, plant and equipment, and investments in associates, are located by region as follows:

(EUR'000)	2025	2024
Non-current segment assets [1]		
North America	74,651	76,677
Europe [2]	108,064	39,640
Total non-current segment assets	**182,715**	**116,317**

(1) From 2025, non-current segment assets include investments in associates. Comparatives have been restated for comparative purposes.

(2) As of December 31, 2025 and December 31, 2024, intangible assets and property, plant and equipment of €33.6 million and €27.9 million, respectively, is located in Denmark, the country of domicile. In addition, as of December 31, 2025 and December 31, 2024, intangible assets and property, plant and equipment of €71.8 million and €11.6 million, respectively, is located in Germany.

Note 7—Employee costs

(EUR'000)	2025	2024	2023
Employee costs			
Wages and salaries	227,118	173,474	170,278
Share-based payment	116,171	95,512	66,660
Pensions (defined contribution plans)	6,921	4,485	4,403
Social security costs	21,134	15,003	12,877
Other employee costs	5,221	4,061	4,238
Total employee costs	**376,565**	**292,535**	**258,456**
Included in the profit or loss			
Cost of sales [1]	20,474	16,487	15,748
Research and development expenses	145,673	131,867	127,002
Selling, general and administrative expenses	210,418	144,181	115,706
Total employee costs	**376,565**	**292,535**	**258,456**
Average number of employees	1,103	892	851

(1) Includes employee costs capitalized as part of inventories.

Key Management Personnel comprises the Board of Directors and the Executive Board and Non-executive Senior Management ("Senior Management"). Compensation to Key Management Personnel comprises salaries, participation in annual bonus schemes, pensions (defined contributions plans), and share-based compensation. Share-based compensation is elaborated in further details in Note 8, "Share-based Payment."

Compensation to Key Management Personnel included in total employee costs is summarized below:

	Board of Directors [1]			Executive Board [2]			Non-executive Senior Management		
(EUR'000)	2025	2024	2023	2025	2024	2023	2025	2024	2023
Compensation									
Wages and salaries	442	482	543	5,466	4,148	4,375	6,466	3,286	4,673
Share-based payment	2,425	2,169	1,276	18,568	18,334	13,243	14,464	10,266	9,529
Pensions (defined contribution plans)	—	—	—	73	57	54	136	98	122
Social security costs	—	—	—	598	118	103	316	52	45
Other employee cost	—	—	—	20	20	20	40	25	40
Total compensation	**2,867**	**2,651**	**1,819**	**24,725**	**22,677**	**17,795**	**21,422**	**13,727**	**14,409**

(1) The Board of Directors comprised six persons in 2025, 2024 and 2023.

(2) The Executive Board comprised four persons in 2025, 2024 and 2023.

Note 8—Share-based Payment

As an incentive to the Senior Management, other employees, members of the Board and select consultants, Ascendis Pharma A/S has established warrant programs, a Restricted Stock Unit ("RSU") program adopted in December 2021, and a Performance Stock Unit ("PSU") program adopted in February 2023, which are all classified as equity-settled share-based payment transactions. Share-based compensation costs are determined using the grant date fair value and are recognized over the vesting period as research and development expenses, selling, general and administrative expenses, or cost of sales.

Restricted Stock Unit Program

RSUs are granted by the Board to members of Senior Management, other employees and members of the Board (the "RSU-holders"), as stipulated in the program. In addition, RSUs may be granted to select consultants.

One RSU represents a right for the RSU-holder to receive one ADS representing ordinary shares of Ascendis Pharma A/S upon vesting, if the vesting conditions are met.

Performance Stock Unit Program

PSUs are granted by the Board to certain members of Senior Management (the "PSU-holders"), as stipulated in the program. In addition, PSUs may be granted to other employees, select consultants and members of the Board. One PSU represents a right for the PSU-holder to receive one ADS representing ordinary shares of Ascendis Pharma A/S upon vesting.

Vesting Conditions

RSUs granted vest over a predetermined service period, and accordingly require RSU-holders to be employed, or provide a specified period of service ("service conditions"). RSUs vest over three years with 1/3 of the RSUs vesting on each anniversary date from the date of grant. RSUs generally cease to vest from the date of termination of employment, or for the Board, termination of board membership, whereas unvested RSUs will lapse.

One PSU represents a right for the PSU-holder to receive one ADS representing ordinary shares of Ascendis Pharma A/S upon vesting. PSUs vest in a manner similar to the service conditions of the RSUs. In addition to service conditions, vesting is also contingent upon achievement of performance-based targets as determined by the Board, provided that no more than 10% of each tranche may be directly attributable to accomplishment of financial results achieved in the financial year prior to the vesting date for PSUs granted in 2023, and upon achievement of long-term strategic goals as evaluated by the Board no later than two weeks prior to each vesting date. Exceeding performance targets will not result in vesting of more PSUs than 100%, nor will it result in additional grants.

RSUs and PSUs generally cease to vest from the date of termination of employment or board membership, as applicable, whereas unvested RSUs or PSUs will be forfeited. The Board may at its discretion and on an individual basis decide to deviate from the vesting conditions, including deciding to accelerate vesting in the event of termination of employment or board membership, as applicable.

Settlement Options

All RSUs and PSUs are settled at the time of vesting by transfer of treasury shares that are ADSs repurchased in the market. In jurisdictions where the Company is required to withhold and settle tax with the tax authority on behalf of the RSU/PSU-holders, the Company withholds the number of RSUs or PSUs that are equal to the estimated monetary value of the RSU/PSU-holders tax obligation from the total number of RSUs or PSUs that otherwise would have been transferred to the RSU/PSU holder upon vesting. These settlements are presented as "Net settlement under stock incentive programs" in the consolidated statement of equity. The Company may at its sole discretion choose to make a cash settlement instead of delivering ADSs.

Adjustments

RSU-holders and PSU-holders are entitled to an adjustment of the number of RSUs or PSUs granted, in the event of certain corporate changes, including among other events, increases or decreases to the share capital at a price below or above market value, the issuance of bonus shares, and changes in the nominal value of each share. In addition, the RSU and PSU Programs contain provisions to accelerate vesting, or compensate with grant of new equity instruments, in the event of restructuring events including change in control events.

RSU and PSU Activity

The following table specifies the number of RSUs and PSUs outstanding:

	Restricted Stock Units	Performance Stock Units	Total
		(Number)	
Outstanding			
January 1, 2023	82,492	—	82,492
Granted during the year [(1)]	609,860	112,268	722,128
Settled during the year	(18,132)	—	(18,132)
Transferred during the year	(20,098)	—	(20,098)
Forfeited during the year	(77,497)	(7,245)	(84,742)
December 31, 2023	**576,625**	**105,023**	**681,648**
Granted during the year [(1)]	717,980	92,655	810,635
Transferred during the year	(212,160)	(35,007)	(247,167)
Forfeited during the year	(88,638)	(6,004)	(94,642)
December 31, 2024	**993,807**	**156,667**	**1,150,474**
Granted during the year [(1)]	634,589	73,583	708,172
Settled during the year	(60,056)	(15,716)	(75,772)
Transferred during the year	(321,351)	(46,588)	(367,939)
Forfeited during the year	(67,161)	(2,688)	(69,849)
December 31, 2025	**1,179,828**	**165,258**	**1,345,086**
Specified by vesting date			
2026	566,011	86,659	652,670
2027	411,030	54,066	465,096
2028	202,787	24,533	227,320
December 31, 2025	**1,179,828**	**165,258**	**1,345,086**

(1) The fair value of RSUs and PSUs is determined on the basis of the closing ADS price on the grant date. The fair value of one RSU and one PSU at the date of grant was €150.40, €141.01 and €105.96 for the years ended December 31, 2025, 2024 and 2023, respectively.

Warrant Program

Warrants are granted by the Board in accordance with authorizations given to it by the shareholders of Ascendis Pharma A/S to all employees, members of the Board and select consultants (“warrant-holders”). Each warrant carries the right to subscribe for one ordinary share of a nominal value of DKK 1. The exercise price is equal to the fair market value of the Company’s ordinary shares at the time of grant as determined by the Board. Apart from exercise prices, exercise periods and vesting conditions for board members, the programs are similar.

Vesting Conditions

Warrants granted vest over a predetermined service period and require warrant-holders provide a specified period of service. Warrants generally cease to vest from the date of termination. In relation to board members, the vesting shall cease on the termination date of the board membership regardless of the reason. In relation to consultants, the vesting shall cease on the termination date of the consultancy relationship. The warrant-holder will, however, be entitled to exercise vested warrants in the exercise periods after termination.

In the event that the employment contract is terminated, and the employee has not given the Company good reason to do so, the warrant-holder may keep the right to continued vesting and exercise of warrants as if the employment was still in effect. In such case, any expense not yet recognized for the outstanding warrants is recognized immediately.

For warrants granted to employees and consultants, 25% of the warrants vest one year after the date of grant, and the remaining 75% of the warrants granted vest over 36 months, with 1/36 of the warrants vesting per month, from one year after the date of grant.

For warrants granted to board members upon the board members accession, 25% of the warrants vest one year after the date of grant, and the remaining 75% of the warrants granted vest over 36 months, with 1/36 of the warrants vesting per month, from one year after the date of grant. Regarding subsequent grants of warrants to board members, 50% of the warrants vest one year after the date of grant, and the remaining 50% of the warrants vest over 12 months, with 1/12 per month from one year after the date of grant.

Exercise Periods

Vested warrants may be exercised during certain exercise periods each year, within certain periods after publication of earnings data of a fiscal quarter, interim and annual reports, as per each program's terms and conditions.

Warrants expire ten years after the grant date. 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 the Company at the time the warrants are exercised. If the consultant's, advisor's or board member's relationship with the Company should cease without this being attributable to the 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 corporate changes.

Events giving rise to an adjustment include, among other things, increases or decreases to the share capital at a price below or above market value, the issuance of bonus shares, changes in the nominal value of each share, and payment of dividends in excess of 10% of the Company's equity.

Warrant Activity

The following table specifies the number and weighted average exercise prices of, and movements, in warrants:

	Warrants (number)	Weighted Average Exercise Price (EUR)
Outstanding		
January 1, 2023	6,864,011	81.30
Granted during the year	395,275	91.07
Exercised during the year [(1)]	(555,144)	17.76
Forfeited during the year	(180,358)	115.79
December 31, 2023	**6,523,784**	**86.38**
Vested at the reporting date	**5,273,056**	**80.02**
Granted during the year	504,105	122.48
Exercised during the year [(1)]	(682,048)	43.35
Forfeited during the year	(141,719)	107.85
December 31, 2024	**6,204,122**	**93.25**
Vested at the reporting date	**5,226,643**	**89.33**
Granted during the year	434,883	148.06
Exercised during the year [(1)]	(1,287,921)	68.76
Forfeited during the year	(128,243)	109.52
Expired during the year	(250)	15.68
December 31, 2025	**5,222,591**	**103.24**
Vested at the reporting date	**4,419,487**	**97.98**

(1) The weighted average share price (listed in $) at the date of exercise was €162.08, €135.86 and €98.10 for the years ended December 31, 2025, 2024 and 2023, respectively.

At December 31, 2025, the Board was authorized to grant up to 1,725,233 additional warrants to employees, board members and select consultants without preemptive subscription rights for the shareholders of Ascendis Pharma A/S.

The following table specifies the weighted average exercise prices and weighted average remaining contractual life for outstanding warrants at December 31, 2025 per grant year.

	Outstanding Warrants (number)	Weighted Average Exercise Price (EUR)	Weighted Average Remaining Life (months)
Granted before January 1, 2023	4,208,147	97.25	50
Granted in 2023	175,231	92.48	89
Granted in 2024	430,190	122.52	102
Granted in 2025	409,023	149.15	113
Outstanding at December 31, 2025	**5,222,591**	**103.24**	**61**

At December 31, 2025, the exercise prices of outstanding warrants under the Company's warrant programs range from €11.98 to €180.65 depending on the grant dates.

The range of exercise prices for outstanding warrants was €11.98 to €145.50 for the years ended December 31, 2024 and 2023. The weighted average remaining life for outstanding warrants was 65 months and 71 months, for the years ended December 31, 2024 and 2023, respectively.

Warrant Compensation Costs

Warrant compensation costs are determined with basis in the grant date fair value of the warrants granted and recognized over the vesting period. Fair value of the warrants is calculated at the grant dates by use of the Black-Scholes option-pricing model with the following assumptions: (1) an exercise price equal to the estimated market price of the Company's shares at the date of grant; (2) an expected lifetime of the warrants determined as a weighted average of the time from grant date to date of becoming exercisable and from grant date to expiry of the warrants; (3) a risk-free interest rate equaling the effective interest rate on a Danish government bond with the same lifetime as the warrants; (4) no payment of dividends; and (5) an expected volatility using the Company's own share price.

The following table summarizes the input to the Black-Scholes option-pricing model and the calculated fair values for warrant grants in 2025, 2024 and 2023:

	2025	2024	2023
Expected volatility	49-50%	50%	49-51%
Risk-free interest rate	2.00 - 2.32%	1.71 - 2.57%	2.40 - 2.97%
Expected life of warrants (years)	6.0	6.0	6.0
Weighted average exercise price	€ 148.06	€ 122.48	€ 91.07
Fair value of warrants granted in the year	€ 56.45 - 87.55	€ 50.86 - 70.39	€ 37.34 - 52.03

Note 9— Principal Accountant Fees and Services

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

(EUR'000)	2025	2024	2023
Principal accountant fees and services			
Audit fees	840	811	739
Audit-related fees	11	147	—
Tax fees	—	91	122
Total principal accountant fees and services	**851**	**1,049**	**861**

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

(EUR'000)	2025	2024	2023
Tax on profit/(loss) for the year			
Current tax (expense)/income	(12,556)	(3,289)	(5,377)
Current tax, adjustments to prior years	513	(126)	3,904
Deferred tax, movement for the year	(3,410)	(2,035)	(1,044)
Deferred tax, adjustments to prior years	70	607	(4,786)
	(15,383)	**(4,843)**	**(7,303)**
Tax for the year can be explained as follows			
Profit/(loss) before tax	(212,651)	(373,241)	(474,144)
Tax at the Danish corporation tax rate of 22%	**46,783**	**82,113**	**104,312**
Tax effect of:			
Non-deductible costs	29,358	(9,740)	(8,494)
Additional tax deductions	37,715	3,161	9,077
Impact from associates	3,588	(4,413)	(4,047)
Prior year adjustments	583	481	(1,294)
Other effects including effect of different tax rates	(2,121)	182	(882)
Deferred tax assets, not recognized	(131,289)	(76,627)	(105,975)
Tax on profit/(loss) for the year	**(15,383)**	**(4,843)**	**(7,303)**
Effective tax rate	**7.23%**	**1.30%**	**1.54%**
Development in deferred tax assets/(liabilities)			
January 1,	(7,258)	(5,830)	—
Deferred income tax (expense)/income, through profit or loss	(3,340)	(1,428)	(5,830)
Foreign exchange translation	975	—	—
December 31,	**(9,623)**	**(7,258)**	**(5,830)**
Specification of deferred tax assets/(liabilities)			
Tax deductible losses	430,011	434,997	521,697
Other temporary differences, assets	291,759	164,479	16,256
Deferred tax assets, not recognized	(721,631)	(599,476)	(537,953)
Other temporary differences, liabilities	(9,762)	(7,258)	(5,830)
Total deferred tax assets/(liabilities) at December 31	**(9,623)**	**(7,258)**	**(5,830)**

Deferred Tax Assets, Not Recognized

Deferred tax assets have not been recognized in the consolidated statements of financial position as of December 31, 2025, due to uncertainty relating to future utilization. The majority of the deferred tax asset can be carried forward without timing limitations, however tax credits can only be deducted in future payable taxes over a period up to 20 years.

As of December 31, 2025, the Company has tax losses carried forward and other temporary deductible differences with a gross amount of €3,280.0 million. The deferred tax assets, not recognized of €721.6 million, mainly attributable to tax-losses carried forward, future R&D depreciations, future tax deductions related to share based payments, additional tax deductions related to up-lift on R&D expenses and additional tax deductions related to tax credits.

The Company had tax losses carried forward of €1,954.6 million at December 31, 2025 and €1,946.2 million and €2,371.3 million as of December 31, 2024 and 2023, respectively.

Tax losses can be carried forward infinitely, where certain limitations exist for amounts to be utilized each year. Under Danish tax legislation, tax losses may be partly refunded by the tax authorities to the extent such tax losses arise from research and development activities. The jointly taxed Danish entities had a negative taxable income and accordingly were entitled to a tax refund of approximately €0.7 million for each of the years ended December 31, 2025, 2024 and 2023.

Other temporary differences include future tax deductions related to share based payments (Warrants, RSUs and PSUs). Tax deductions can be taken when the warrants/RSUs/PSUs are exercised/transferred. For the year ended December 31, 2025, the future tax deductions have been estimated to have a tax value of €67.0 million compared to €21.7 million and €10.6 million for the years ended December 31, 2024 and 2023, respectively. These future tax deductions depend on the future share price, timing and amounts of warrants/RSUs/PSUs exercises/transfers, and accordingly, the future tax deductions are subject to uncertainties. Refer to Note 8, "Share-based Payment," regarding a description of warrant and RSU/PSU programs.

For the year ended December 31, 2025, the Company is entitled to additional future tax deduction related to uplift on R&D deductions and tax credits with a total tax value of €29.7 million compared to 24.8 and €8.4 million for the years ended December 31, 2024 and 2023, respectively. Additional future tax deductions are included in other temporary differences.

International Tax Reform - Pillar Two Model Rules

On May 23, 2023, the IASB issued "International Tax Reform - Pillar Two Model Rules - Amendments to IAS 12," which clarifies that IAS 12 applies to income taxes arising from tax law enacted or substantively enacted to implement the Pillar Two model rules published by the OECD/G20 Inclusive Framework on Base Erosion and Profit Shifting Pillar Two model rules. The Company has adopted these amendments; however, they are not applicable for the year ended December 31, 2025, as the Company's consolidated revenue is currently below the threshold of €750 million.

Uncertain Tax Positions

The Company operates across numerous tax jurisdictions with complex, interpretative legislation. Management evaluates uncertain tax positions to ensure proper recognition and measurement of tax assets and liabilities.

Note 11—Intangible Assets

(EUR'000)	Goodwill	Software	Total
Cost			
January 1, 2024	3,495	2,296	5,791
Additions	—	76	76
December 31, 2024	**3,495**	**2,372**	**5,867**
Additions	—	172	172
December 31, 2025	**3,495**	**2,544**	**6,039**
Amortization and impairment			
January 1, 2024	—	(1,372)	(1,372)
Amortization charge	—	(467)	(467)
December 31, 2024	**—**	**(1,839)**	**(1,839)**
Amortization charge	—	(490)	(490)
December 31, 2025	**—**	**(2,329)**	**(2,329)**
Carrying amount			
December 31, 2024	**3,495**	**533**	**4,028**
December 31, 2025	**3,495**	**215**	**3,710**

At the reporting date, no internally generated intangible assets from development of pharmaceutical drug candidates have been recognized. Thus, all related research and development expenses incurred for the years ended December 31, 2025, 2024 and 2023, were recognized in the consolidated statements of profit or loss.

Goodwill relates to the acquisition of Complex Biosystems GmbH (now Ascendis Pharma GmbH) in 2007. Goodwill was calculated as the excess amount of the purchase price to the fair value of identifiable assets acquired, and liabilities assumed at the acquisition date. Ascendis Pharma GmbH was initially a separate technology platform company but is now an integral part of the Company's research and development activities. Accordingly, it is not possible to look separately at Ascendis Pharma GmbH when considering the recoverable amount of the goodwill. Goodwill is monitored and tested for impairment on a consolidated level as the Company is considered to represent one cash-generating unit.

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

Note 12—Property, Plant and Equipment

(EUR'000)	Plant and Machinery	Other Equipment	Leasehold Improve-ments	Right-of-Use Assets	Total
Cost					
January 1, 2024	27,436	11,420	19,375	123,920	182,151
Additions	299	951	76	861	2,187
Disposals	(5,995)	(1,635)	—	(89)	(7,719)
Transferred	66	(66)	—	—	—
Foreign exchange translation	127	306	847	5,462	6,742
December 31, 2024	**21,933**	**10,976**	**20,298**	**130,154**	**183,361**
Additions	996	5,704	1,678	78,646	87,024
Transferred [(1)]	(162)	(1,311)	(13,658)	(21,264)	(36,395)
Foreign exchange translation	(2)	(517)	(1,271)	(9,299)	(11,089)
December 31, 2025	**22,765**	**14,852**	**7,047**	**178,237**	**222,901**
Depreciation and impairment					
January 1, 2024	(12,784)	(7,175)	(10,946)	(40,612)	(71,517)
Depreciation charge	(2,330)	(1,322)	(1,283)	(12,312)	(17,247)
Disposals	5,296	1,501	—	88	6,885
Foreign exchange translation	(112)	(194)	(556)	(1,906)	(2,768)
December 31, 2024	**(9,930)**	**(7,190)**	**(12,785)**	**(54,742)**	**(84,647)**
Depreciation charge	(2,325)	(1,301)	(1,230)	(12,350)	(17,206)
Impairment charge	—	(196)	(618)	(6,694)	(7,508)
Impairment reversal	16	201	2,008	—	2,225
Transferred [(1)]	529	731	11,667	12,797	25,724
Foreign exchange translation	(18)	368	793	3,847	4,990
December 31, 2025	**(11,728)**	**(7,387)**	**(165)**	**(57,142)**	**(76,422)**
Carrying amount					
December 31, 2024	**12,003**	**3,786**	**7,513**	**75,412**	**98,714**
December 31, 2025	**11,037**	**7,465**	**6,882**	**121,095**	**146,479**

(1) Includes transfer from right-of-use assets to finance lease receivables. For further details, refer to Note 17, "Financial Assets and Liabilities."

The impairment charge for the year ended December 31, 2025, relates to change in activities at one of the Company's sites. The site is partially subleased (commencing in 2026) and is recognized as a right-of-use asset with a carrying amount of €30.9 million as of December 31, 2025. The impairment charge represents the difference between the carrying amount of the right-of-use subleased asset and the lease receivable, subsequently recognized at the lease commencement date.

Depreciation charges are specified below:

(EUR'000)	2025	2024	2023
Depreciation charges			
Cost of sales [(1)]	1,835	3,197	2,509
Research and development expenses	8,468	7,453	10,296
Selling, general, and administrative expenses	6,903	6,597	5,623
Total depreciation charges	**17,206**	**17,247**	**18,428**

(1) Includes depreciation charges capitalized as part of inventories.

Note 13—Investments in Associates

The Company's associates relate to investments in Eyconis (principal place of business; U.S.), and VISEN (principal place of business; China). The Company's investments in Eyconis and VISEN are accounted for using the equity method in the consolidated financial statements as the Company has determined that it has significant influence over the investments.

Eyconis

In January 2024, the Company announced the formation and launch with Frazier Life Sciences of Eyconis, a separate company created to develop, manufacture, and commercialize TransCon ophthalmology assets globally, together with a $150 million commitment from an investor syndicate that includes Frazier, RA Capital Management, venBio, and HealthQuest Capital. As of December 31, 2025 and 2024, the Company's ownership in Eyconis was 33.2% and 41.6%, respectively. As of December 31, 2025 and 2024, the carrying amount of Eyconis using the equity method was €9.2 million and €13.6 million, respectively.

VISEN

In November 2018, the Company entered into three exclusive license agreements with VISEN for the further development and commercialization of TransCon hGH, TransCon PTH and TransCon CNP in Greater China, and as consideration for the granting of such rights has received a 50.0% ownership of VISEN's issued and outstanding shares. On March 20, 2025, VISEN Pharmaceuticals ("VISEN") announced the pricing of its initial public offering ("IPO") on the Hong Kong Stock Exchange. The IPO closed on March 21, 2025, and VISEN's shares began trading under the stock code 2561.HK. Prior to the IPO the Company's ownership in VISEN was 43.9%. Following the IPO, the Company's ownership in VISEN was 39.2%. As a result, a non-cash gain of €35.7 million was recognized in the consolidated statement of profit or loss as part of share of profit/(loss) of associates. The IPO did not change the accounting treatment of VISEN. As of December 31, 2025 and 2024, the Company's ownership in VISEN was 39.2% and 43.9%, respectively. As of December 31, 2025, VISEN's share price at the Hong Kong Stock Exchange was HK$32.80, reflecting the market value of the Company's equity position of €147.5 million. As of December 31, 2025 and 2024, the carrying amount of VISEN using the equity method was €23.3 million and €0.0 million, respectively.

The management and existing shareholders of VISEN, including Ascendis Pharma, have entered into customary lock-up agreements restricting the sale of VISEN shares for six months following the IPO; additionally, certain significant shareholders of VISEN, including the Company, are subject to an additional lock-up obligation during the period commencing on the date that is six months after the IPO and ending on the date that is 12 months after the IPO during which such shareholders may not sell shares of VISEN to an extent that would cause such shareholder to cease being a controlling shareholder of VISEN pursuant to applicable listing rules.

Financial Statement Information from Associates

The aggregated profit or loss, total comprehensive income as per the associates latest available interim financial statements, transactions and outstanding balances with associates as of December 31, 2025 and 2024 were as follows.

(EUR'000)	2025	2024
Statement of profit or (loss)		
Profit/(loss) for the year from continuing operations	**(47,507)**	**(59,235)**
Total comprehensive income	**(47,490)**	**(59,218)**
Transactions and outstanding balances as of December 31		
Invoicing of goods and services to associates	31,808	18,225
Trade receivables from associates	824	1,759
Contract liabilities	4,944	5,936

Note 14—Inventories

Inventories are specified below:

(EUR'000)	2025	2024
Inventories		
Raw materials and consumables	19,083	17,596
Work in progress	253,494	235,688
Finished goods	28,956	42,325
Total inventories	**301,533**	**295,609**

Due to production lead time, work in progress includes inventories that are not sellable before more than twelve months after the reporting date.

Inventories were reduced by write-downs of €24.9 million and €15.7 million for the years ended December 31, 2025 and 2024 respectively.

Note 15—Contract Liabilities

At December 31, 2025, contract liabilities comprise unsatisfied performance obligations related to delivery of commercial supply under one of the Company's license agreements. Non-current contract liabilities are expected to be recognized as revenue within 1-2 years.

Revenue recognized from contract liabilities were €5.9 million, €1.4 million and €13.3 million for the years ended December 31, 2025, 2024 and 2023, respectively.

Note 16—Provisions

Development in provisions is specified below:

(EUR'000)	2025
Provisions	
January 1	99,149
Additions related to prior years	3,936
Net additions for the year	74,288
Reversals and other adjustments	(639)
Foreign exchange translation	(10,338)
December 31	**166,396**

Note 17—Financial Assets and Liabilities

Financial assets and liabilities comprise the following:

(EUR'000)	2025	2024
Financial assets by category		
Trade receivables	141,333	166,280
Other receivables (excluding indirect tax receivables)		
Lease receivables	10,268	—
Other receivables	9,322	3,964
Cash and cash equivalents	616,041	559,543
Financial assets measured at amortized cost	**776,964**	**729,787**
Total financial assets	**776,964**	**729,787**
Classified in the statement of financial position		
Non-current assets	10,870	2,317
Current assets	766,094	727,470
Total financial assets	**776,964**	**729,787**
Financial liabilities by category		
Borrowings		
Convertible senior notes	429,391	458,207
Royalty funding liabilities	290,871	305,379
Lease liabilities	151,524	93,030
Trade payables and accrued expenses	90,657	96,394
Other liabilities (excluding indirect tax and employee related payables)	1,046	311
Financial liabilities measured at amortized cost	**963,489**	**953,321**
Derivative liabilities	256,231	150,670
Financial liabilities measured at fair value through profit or loss	**256,231**	**150,670**
Total financial liabilities	**1,219,720**	**1,103,991**
Classified in the statement of financial position		
Non-current liabilities	385,254	365,080
Current liabilities	834,466	738,911
Total financial liabilities	**1,219,720**	**1,103,991**

Finance income and expenses are specified below:

(EUR'000)	2025	2024	2023
Finance income			
Interest income	15,301	14,361	16,857
Remeasurement gain of financial liabilities	20,469	11,248	14,654
Foreign exchange translation (net)	78,229	—	12,346
Total finance income	**113,999**	**25,609**	**43,857**
Finance expenses			
Interest expenses	80,647	65,504	44,065
Remeasurement loss of financial liabilities	126,040	7,374	—
Foreign exchange translation (net)	—	27,149	—
Total finance expenses	**206,687**	**100,027**	**44,065**

Interest income and interest expenses relate to financial assets and liabilities measured at amortized cost. Net exchange rate gains and losses primarily relate to U.S. Dollar/Euro fluctuations pertaining to the Company's cash, cash equivalents, marketable securities and borrowings.

Borrowings

Convertible Senior Notes

In March 2022, the Company issued an aggregate principal amount of $575.0 million of fixed rate 2.25% convertible notes. The net proceeds from the offering of the convertible notes were $557.9 million (€503.3 million) after deducting the initial purchasers' discounts and commissions and offering expenses. The convertible notes rank equally in right of payment with all future senior unsecured indebtedness. Unless earlier converted or redeemed, the convertible notes will mature on April 1, 2028.

The convertible notes accrue interest at a rate of 2.25% per annum, payable semi-annually in arrears on April 1 and October 1 of each year. At any time before the close of business on the second scheduled trading day immediately before the maturity date, noteholders may convert their convertible notes at their option into the Company's ordinary shares represented by ADSs, together, if applicable, with cash in lieu of any fractional ADS, at the then-applicable conversion rate. The initial conversion rate is 6.0118 ADSs per $1,000 principal amount of convertible notes, which represents an initial conversion price of $166.34 per ADS. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events.

The convertible notes will be optionally redeemable, in whole or in part (subject to certain limitations), at the Company's option at any time, and from time to time, on or after April 7, 2025, but only if the last reported sale price per ADS exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related optional redemption notice; and (ii) the trading day immediately before the date the Company sends such notice.

On December 31, 2025, the carrying amount of the convertible notes was €429.4 million, and the disclosed fair value was €426.4 million. Fair value cannot be measured based on quoted prices in active markets or other observable input, and accordingly the fair value was, from 2025, measured by using input from the private placement market. Up until 2024, the fair value the fair value was measured by using an estimated market rate for an equivalent non-convertible instrument.

Royalty Funding Liabilities

The Company has entered into capped synthetic royalty funding agreements with Royalty Pharma (the "Purchaser"), which is presented as part of borrowings, and represents the Company's contractual obligations to pay a predetermined percentage of future commercial revenue until reaching a predetermined multiple of proceeds received, according to the detailed provisions of the synthetic royalty funding agreements.

On December 31, 2025, the carrying amount of the royalty funding liabilities was €290.9 million, and the disclosed fair value was €296.9 million. Fair value cannot be measured based on quoted prices in active markets or other observable input, and accordingly the fair value was measured by using an estimated market rate for an equivalent instrument.

YORVIPATH Agreement

In September 2024, the Company entered into a $150.0 million capped synthetic royalty funding agreement (the "Royalty Pharma Yorvipath Agreement") with the Purchaser. The net proceeds were $148.2 million (€134.2 million) after deducting offering expenses.

Under the terms of the Royalty Pharma Yorvipath Agreement, the Company received an upfront payment of $150.0 million (the "Yorvipath Purchase Price") in exchange for a 3% royalty on net revenue from sales of YORVIPATH in the U.S. (the "Yorvipath Revenue Payments"). The Yorvipath Revenue Payments to the Purchaser will cease upon reaching a multiple of the Yorvipath Purchase Price of 2.0 times, or 1.65 times if the Purchaser receives Yorvipath Revenue Payments in that amount by December 31, 2029.

The Royalty Pharma Yorvipath Agreement includes a buy-out option, which provides the Company with the right to settle all outstanding liabilities at any time by paying a buy-out amount equal to 2.0 times the Yorvipath Purchase Price minus the Yorvipath Revenue Payments paid to the Purchaser as of the effective date of the buy-out notice. However, if the buy-out notice is provided on or prior to September 30, 2028, and the Company has paid the Purchaser, Yorvipath Revenue Payments equal to the Yorvipath Purchase Price as of the date of the buy-out notice, then the buy-out amount is equal to 1.65 times the Yorvipath Purchase Price minus the Yorvipath Revenue Payments paid to the Purchaser as of the effective date of the buy-out notice.

SKYTROFA Agreement

In September 2023, the Company entered into a $150.0 million capped synthetic royalty funding agreement (the "Royalty Pharma Skytrofa Agreement") with the Purchaser. The net proceeds were $146.3 million (€136.3 million) after deducting offering expenses.

Under the terms of the Royalty Pharma Skytrofa Agreement, the Company received an upfront payment of $150.0 million (the "Skytrofa Purchase Price") in exchange for a 9.15% royalty on net revenue from sales of SKYTROFA in the U.S., beginning on January 1, 2025 (the "Skytrofa Revenue Payments"). The Skytrofa Revenue Payments to the Purchaser will cease upon reaching a multiple of the Skytrofa Purchase Price of 1.925 times, or 1.65 times if the Purchaser receives Skytrofa Revenue Payments in that amount by December 31, 2031.

The Royalty Pharma Skytrofa Agreement includes a buy-out option, which provides the Company with the right to settle all outstanding liabilities at any time by paying a buy-out amount equal to 1.925 times the Skytrofa Purchase Price minus the Skytrofa Revenue Payments paid to the Purchaser as of the effective date of the buy-out notice. However, if the buy-out notice is provided on or prior to December 31, 2028, and the Company has paid the Purchaser, Skytrofa Revenue Payments equal to the Skytrofa Purchase Price as of the date of the buy-out notice, then the buy-out amount is equal to 1.65 times the Skytrofa Purchase Price minus the Skytrofa Revenue Payments paid to the Purchaser as of the effective date of the buy-out notice.

Leases

The Company primarily leases offices and laboratory facilities. Lease arrangements contain a range of different terms and conditions and are typically entered into for fixed periods. In order to improve flexibility to the Company's operations, lease arrangements may provide the Company with option to extend the lease or terminate the lease within the enforceable lease term. In the Company's current lease portfolio, extension and termination options are up to ten years, in addition to the non-cancellable periods. These lease arrangements are recognized as right-of-use assets and lease liabilities ("lease activities"). In addition, the Company enter into various lease arrangements of assets with low value and/or on short term basis (12 months or less).

The following expenses related to lease activities were recognized in the consolidated statements of profit or loss:

(EUR'000)	2025	2024	2023
Lease expenses			
Depreciation	12,350	12,312	11,875
Lease interest	4,186	3,303	3,581
Total lease expenses	**16,536**	**15,615**	**15,456**

Financing Activities

The development in borrowings related to financing activities is specified below:

		Cash payments		Non-cash items				
(EUR'000)	Beginning of year	Repay-ments	Net proceeds	Additions/ (disposals)	Remeasure-ments	Accretion of interest	Foreign exchange translation	End of year
Financing activities								
December 31, 2025								
Borrowings (excluding lease liabilities)	763,586	(29,065)	—	—	10	76,247	(90,516)	720,262
Lease liabilities	93,030	(15,548)	—	78,517	—	4,186	(8,661)	151,524
Total financing activities	**856,616**	**(44,613)**	**—**	**78,517**	**10**	**80,433**	**(99,177)**	**871,786**
Financing activities								
December 31, 2024								
Borrowings (excluding lease liabilities)	545,472	(11,819)	134,158	—	(11,248)	62,116	44,907	763,586
Lease liabilities	98,793	(14,677)	—	861	—	3,303	4,750	93,030
Total financing activities	**644,265**	**(26,496)**	**134,158**	**861**	**(11,248)**	**65,419**	**49,657**	**856,616**

Derivative Liabilities

Derivative liabilities relate to the foreign currency conversion option embedded in the convertible notes.

Fair value cannot be measured based on quoted prices in active markets or other observable inputs and accordingly, derivative liabilities are measured by using the Black-Scholes option-pricing model. Fair value of the option is calculated, applying the following assumptions: (1) conversion price; (2) the Company's share price; (3) maturity of the option; (4) a risk-free interest rate equaling the effective interest rate on a U.S. government bond with the same lifetime as the maturity of the option; (5) no payment of dividends; and (6) an expected volatility using the Company's share price (48.9% and 49.6% as of December 31, 2025 and December 31, 2024, respectively).

For additional description of fair values, refer to the following section "Fair Value Measurement."

Sensitivity Analysis

On December 31, 2025, all other inputs and assumptions held constant, a 10% relative increase in volatility, will increase the fair value of derivative liabilities by approximately €13.2 million and indicates a decrease in profit or loss and equity before tax. Similarly, a 10% relative decrease in volatility indicates the opposite impact.

Similarly, on December 31, 2025, all other inputs and assumptions held constant, a 10% increase in the share price, will increase the fair value of derivative liabilities by approximately €50.8 million and indicates a decrease in profit or loss and equity before tax. Similarly, a 10% decrease in the share price indicates the opposite impact.

Fair Value Measurement

Because of the short-term maturity for cash and cash equivalents, receivables and trade payables, their fair value approximate carrying amount. Fair value of lease liabilities are not disclosed. Fair value compared to carrying amount of convertible notes, royalty funding liabilities and derivatives, and their level in the fair value hierarchy is summarized in following table, where;

Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date;

Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and

Level 3 inputs are unobservable inputs for the asset or liability.

	2025		2024		
(EUR'000)	**Carrying amount**	**Fair value**	**Carrying amount**	**Fair value**	**Fair value level**
Convertible senior notes	429,391	426,429	458,207	438,288	2
Royalty funding liabilities	290,871	296,899	305,379	305,673	3
Financial liabilities measured at amortized cost	**720,262**	**723,328**	**763,586**	**743,961**	
Derivative liabilities	256,231	256,231	150,670	150,670	3
Financial liabilities measured at fair value through profit or loss	**256,231**	**256,231**	**150,670**	**150,670**	

The following table specifies movements in level 3 fair value measurements:

(EUR'000)	**2025**	**2024**	**2023**
Derivative liabilities			
January 1	150,670	143,296	157,950
Remeasurement recognized in financial income or expense	105,561	7,374	(14,654)
December 31	**256,231**	**150,670**	**143,296**

Note 18 – Financial Risk Management

The Company manages capital to ensure that all group enterprises will be able to continue as a going concern while maximizing the return to shareholders through the optimization of debt and equity balances.

Capital Structure

The Company's capital structure consists of equity and external debt obtained through issuance of convertible notes and royalty funding liabilities. The Company is not subject to any contractually imposed capital requirements or financial covenants. The capital structure is reviewed on an ongoing basis for the adequacy of the Company's capital compared to the resources required for carrying out ordinary activities.

Development in the Company's share capital and treasury shares reserves are described in the following sections. Other equity reserves are described in Note 2, "Summary of Material Accounting Policies."

Share Capital

The share capital of Ascendis Pharma A/S consists of 61,977,408 fully paid shares at a nominal value of DKK 1, all in the same share class, and which includes 597,096 ordinary shares represented by ADSs held by Ascendis Pharma A/S.

The development in outstanding shares of the Company was as follows:

	2025	2024	2023	2022	2021
			(Number)		
Changes in share capital					
January 1	60,689,487	57,707,439	57,152,295	56,937,682	53,750,386
Increase through cash contributions	1,287,921	2,982,048	555,144	214,613	3,187,296
December 31	**61,977,408**	**60,689,487**	**57,707,439**	**57,152,295**	**56,937,682**

Capital increases in 2024 and 2021 were impacted by follow-on public offerings with net proceeds of €290.6 and €367.9 million, respectively.

Treasury Shares Reserve

The development in the holding of treasury shares was as follows:

	Nominal value	Holding	Holding in % of total outstanding shares
	(EUR'000)	(Number)	
Treasury shares			
January 1, 2024	146	1,093,054	—
Transferred under stock incentive programs	(33)	(247,167)	—
December 31, 2024	**113**	**845,887**	**1.4%**
Acquired from third parties	16	119,148	—
Transferred under stock incentive programs	(49)	(367,939)	—
December 31, 2025	**80**	**597,096**	**1.0%**

Financial Risk Management Objectives

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

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

Market Risk

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

Foreign Currency Risk Management

The Company is exposed to foreign currency exchange risks arising from various currency exposures, primarily with respect to the U.S. Dollar ("USD"). Foreign currency exchange risks to the USD are unchanged to prior year, and primarily relate to sales and purchases in foreign currencies, convertible notes and royalty funding liabilities, countered by cash and cash equivalents. The exposure from foreign currency exchange risks is managed by maintaining cash positions in the currencies in which the majority of future expenses are denominated, and payments are made from those reserves.

Foreign Currency Sensitivity Analysis

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

		Hypothetical impact on consolidated financial statements		
	Nominal positions (net)	Increase in foreign currency exchange rate	Profit/(loss) before tax	Equity before tax
		(EUR '000)		
USD/EUR				
December 31, 2025	(508,858)	10%	(50,886)	(50,886)
December 31, 2024	(735,064)	10%	(73,506)	(73,506)

Interest Rate Risk Management

Outstanding convertible notes comprise a 2.25% coupon fixed rate structure. Further, the effective interest rate on royalty funding liabilities is estimated at initial recognition and takes into account anticipated amount and timing of future cash flows, which further depends on future commercial revenue forecasts and the probability of exercising the embedded buy-out option. Material changes to anticipated future cash flows could potentially increase or decrease future interest expense. In addition, the interest rate on lease liabilities is fixed at the lease commencement date.

Future indebtedness, including those related to lease arrangements, if any, may be subject to higher interest rates. In addition, future interest income from interest-bearing bank deposits may fall short of expectations due to changes in interest rates.

Derivative liabilities are measured at fair value through profit or loss. Since the fair value is exposed from the development in interest rates, the profit or loss is exposed to volatility from such development.

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

Credit Risk Management

The Company has adopted an investment policy with the primary purpose of preserving capital, fulfilling liquidity needs and diversifying the risks associated with cash, cash equivalents and marketable securities. This investment policy establishes minimum ratings for institutions with which the Company holds cash and cash equivalents, as well as rating and concentration limits for marketable securities held. All material counterparties are considered creditworthy. While the concentration of credit risk may be significant, the credit risk for each individual counterpart is considered to be low. The exposure to credit risk primarily relates to cash and cash equivalents. The credit risk on bank deposits is limited because the counterparties, holding significant deposits, are banks with minimum credit-ratings of A3/A- assigned by international credit-rating agencies.

The majority of cash and cash equivalents are held in accounts at major financial institutions, and the deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where cash and cash equivalents are held, there can be no assurance that uninsured funds are accessible in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect the business and financial position. The banks are reviewed on a regular basis and deposits may be transferred during the year to mitigate credit risk.

In order to mitigate the concentration of credit risks on bank deposits and to preserve capital, a portion of the bank deposits may be placed into investment grade rated marketable securities. The Company's investment policy, approved by the Board, only allows investment in marketable securities having investment grade credit-ratings, assigned by international credit-rating agencies. As of December 31, 2025, the Company do not hold marketable securities.

On each reporting date, the risk of expected credit loss on bank deposits and marketable securities, if any, including the hypothetical impact arising from the probability of default, is considered in conjunction with the expected loss caused by default by banks or securities with similar credit-ratings and attributes. In line with previous periods, this assessment did not reveal a material impairment loss, and accordingly no provision for expected credit loss has been recognized.

At the reporting dates, there are no significant overdue trade receivable balances. As a result, write-down to accommodate expected credit-losses is not deemed material.

Liquidity Risk Management

Historically, the risk of insufficient funds has been addressed through proceeds from sale of the Company's securities in private and public offerings, through issuance of convertible notes in 2022, and through royalty funding liabilities in 2024 and 2023.

Liquidity risk is managed by maintaining adequate cash reserves. The risk of shortage of funds is monitored, through the financial forecasting process, to ensure sufficient funds are available to settle liabilities as they fall due. Besides long term deposits on leases and finance lease receivables, the Company's financial assets are recoverable within twelve months after the reporting date.

Maturity analysis

The following table summarizes maturity analysis (on an undiscounted basis) for non-derivative financial liabilities recognized in the consolidated statements of financial position:

(EUR'000)	< 1 year	1-5 years	>5 years	Total contractual cash-flows	Carrying amount
Financial liabilities					
December 31, 2025					
Borrowings (excluding lease liabilities)	51,081	812,294	140,555	1,003,930	720,262
Lease liabilities	20,438	82,299	93,898	196,635	151,524
Trade payables, accrued expenses and other liabilities	91,703	—	—	91,703	91,703
Total financial liabilities	**163,222**	**894,593**	**234,453**	**1,292,268**	**963,489**
Financial liabilities					
December 31, 2024					
Borrowings (excluding lease liabilities)	32,303	1,027,558	13,660	1,073,521	763,586
Lease liabilities	15,482	52,007	39,127	106,616	93,030
Trade payables, accrued expenses and other liabilities	96,705	—	—	96,705	96,705
Total financial liabilities	**144,490**	**1,079,565**	**52,787**	**1,276,842**	**953,321**

"Borrowings (excluding lease liabilities)" comprise convertible notes and royalty funding liabilities. Expected maturity for royalty funding liabilities is based on anticipated amount and timing of future revenue from sale of commercial products. Further details regarding the payment structure of the royalty funding agreements are provided above.

Note 19—Commitments and Contingencies

The Company has agreed minimum commitments related to the manufacturing of product supply, subject to continuous negotiation and adjustments according to the individual contractual terms and conditions. Cost of product supply is recognized when the Company obtains control of the goods. In addition, the Company has commitments related to short-term leases and leases of low value assets, contracts of various lengths in respect of research and development with CROs, and IT and facility related services. Costs relating to those commitments are recognized as services are received.

The Company is not aware of any significant legal claims or disputes.

Note 20—Related Party Transactions

The Board of Directors and Senior Management ("Key Management Personnel") are considered related parties as they have authority and responsibility for planning and directing the Company's operations. Related parties also include undertakings in which such individuals have a controlling or joint controlling interest. Additionally, all group enterprises and associates are considered related parties.

Neither the Company's related parties nor major shareholders hold a controlling, joint controlling, or significant interest in the Group.

The Company has entered into employment agreements with and issued warrants, RSUs and PSUs to Key Management Personnel. In addition, the Company pays fees for board tenure and board committee tenure to the independent members of the Board of Directors. For further details, refer to Note 7, "Employee Costs." Indemnification agreements have been entered with members of the Board of Directors, the Executive Board and Non-executive Senior Management.

Transactions between the parent company and group enterprises comprise management and license fees, research and development services, administration services, and clinical and commercial supplies. These transactions have been eliminated in the consolidated financial statements. Transactions and outstanding balances with the associates are disclosed in Note 13, "Investments in Associates."

In addition, the parent company Ascendis Pharma A/S is jointly taxed with its Danish subsidiaries, where the current Danish corporation tax is allocated between the jointly taxed Danish companies. For further details, refer to Note 10, "Tax on Profit/(Loss) for the Year and Deferred Tax."

Except for the information disclosed above, the Company has not undertaken any significant transactions with members of the Key Management Personnel, or undertakings in which the identified related parties have a controlling or joint controlling interest.

Note 21—Investments in Group Enterprises and Associates

Ascendis Pharma A/S's (parent company) investments in group enterprises and associates at December 31, 2025 comprise:

Subsidiaries	Domicile	Ownership
Ascendis Pharma GmbH	Germany	100%
Ascendis Pharma Endocrinology GmbH	Germany	100%
Ascendis Pharma, LLC	USA	100%
Ascendis Pharma Endocrinology, Inc.	USA	100%
Ascendis Pharma, Ophthalmology Division A/S	Denmark	100%
Ascendis Pharma Endocrinology Division A/S	Denmark	100%
Ascendis Pharma Bone Diseases A/S	Denmark	100%
Ascendis Pharma Growth Disorders A/S	Denmark	100%
Ascendis Pharma Oncology Division A/S	Denmark	100%
Ascendis Pharma Europe A/S	Denmark	100%
Ascendis Pharma UK Limited	United Kingdom	100%
Ascendis Pharma Iberia S.L.	Spain	100%
Ascendis Pharma France SASU	France	100%
Ascendis Pharma Italia S.R.L.	Italy	100%
Ascendis Pharma Sverige AB	Sweden	100%
Ascendis Pharma Switzerland GmbH	Switzerland	100%
Ascendis Pharma Belgium BV	Belgium	100%
ASND Portugal, Unipessoal, Lda.	Portugal	100%

Associates	Domicile	Ownership
VISEN Pharmaceuticals	Cayman Island	39.2%
Eyconis Inc.	USA	33.2%

Note 22—Ownership

The following investors, or groups of affiliated investors, are known by us to beneficially own more than 5% of the Company's outstanding ordinary shares at December 31, 2025:

- Entities affiliated with RA Capital Management, LLC, USA
- Westfield Capital Management Company, L.P., USA
- Entities affiliated with FMR LLC, USA
- Avoro Capital Advisors LLC, USA
- Entities affiliated with Artisan Partners LP, USA
- Entities affiliated with Janus Henderson Group plc, United Kingdom

- Entities affiliated with Capital International Investors

The Company's American Depository Shares are held through BNY (Nominees) Limited as nominee, of The Bank of New York Mellon, UK (as registered holder of the Company's outstanding ADSs).

Note 23—Subsequent Events

On January 9, 2026, the Company announced that our Board has authorized a $120 million share repurchase program (the "Share Repurchase Program"). Purchases under the Share Repurchase Program may be made from time to time through a variety of methods, which may include open-market purchases, privately negotiated transactions, or other methods permitted under applicable securities laws. The timing and amount of any repurchases pursuant to the Share Repurchase Program will be determined based on market conditions, share price and other factors. The Share Repurchase Program does not require the Company to repurchase any specific number of shares, and may be modified, suspended or terminated at any time without notice.

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

Item 19 Exhibits

The following exhibits are filed as part of this annual report:

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	Date	Number	File Number	
1.1	Articles of Association, currently in effect (English translation).	6-K	2/11/2026	1.1	001-36815	
2.1	Deposit Agreement dated January 27, 2015 among Ascendis Pharma A/S The Bank of New York Mellon and Owners and Holders of American Depositary Shares.	F-3	2/2/2016	4.2	333-209336	
2.2	Form of American Depositary Receipt (included in Exhibit 2.1).					
2.3	Description of Share Capital and American Depositary Shares.					X
4.1(a)	Rental Agreement, between Technologiepark Heidelberg II GmbH & Co. KG and Ascendis Pharma GmbH (English translation).	F-1	12/18/2014	10.3(a)	333-201050	
4.1(b)	Supplement No. 1 to Rental Agreement, between Technologiepark Heidelberg II GmbH & Co. KG and Ascendis Pharma GmbH (English translation).	F-1	12/18/2014	10.3(b)	333-201050	
4.2(a)	Reference is made to Exhibit 1.1.					
4.2(b)	Form of Warrant Certificate for Warrants	20-F	2/12/2025	4.2(b)	001-36815	
4.3	Form of Indemnification Agreement for board members and senior management.	F-1	1/16/2015	10.5	333-201050	
4.4	Registration Rights Agreement dated December 11, 2015 by and among Ascendis Pharma A/S, Fidelity Securities Fund: Fidelity Series Small Cap Opportunities Fund—Healthcare Sub and Fidelity Stock Selector Small Cap Fund—Health Care Sub.	6-K	12/14/2015	4.1	001-36815	
4.5*	Lease Agreement dated July 1, 2025 between Ascendis Pharma A/S and Tuborg Havnevej I/S					X
4.6†	Manufacturing and Supply Agreement dated January 12, 2017, between Ascendis Pharma A/S and Medicom Innovation Partner A/S.	20-F	3/28/2018	4.10	001-36815	
4.7*	Exclusive Licence Agreement dated November 7, 2018, between Ascendis Pharma Growth Disorders A/S and VISEN Pharmaceuticals (CNP).	20-F	4/3/2019	4.15	001-36815	
4.8*	Exclusive Licence Agreement dated November 7, 2018, between Ascendis Pharma Endocrinology Division A/S and VISEN Pharmaceuticals (hGH).	20-F	4/3/2019	4.16	001-36815	
4.9*	Exclusive Licence Agreement dated November 7, 2018, between Ascendis Pharma Bone Diseases A/S and VISEN Pharmaceuticals (PTH).	20-F	4/3/2019	4.17	001-36815	

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	Date	Number	File Number	
4.10*	Manufacturing and Supply Agreement dated December 27, 2020, between Ascendis Pharma A/S and Bachem AG.	20-F	3/2/2022	4.16	001-36815	
4.11*	Manufacturing and Supply Agreement dated May 27, 2021, between Ascendis Pharma A/S and Carbogen Amcis AG.	20-F	3/2/2022	4.17	001-36815	
4.12*	Amended and Restated Shareholders Agreement dated January 8, 2021, by and among Ascendis Pharma A/S and the parties set forth therein.	20-F	3/10/2021	4.17	001-36815	
4.13*	Amendment Letter to the Exclusive Licence Agreement dated January 4, 2021 between Ascendis Pharma Growth Disorders A/S and VISEN Pharmaceuticals (CNP).	20-F	3/10/2021	4.18	001-36815	
4.14*	Amendment Letter to the Exclusive Licence Agreement dated January 4, 2021 between Ascendis Pharma Endocrinology Division A/S and VISEN Pharmaceuticals (hGH).	20-F	3/10/2021	4.19	001-36815	
4.15*	Amendment Letter to the Exclusive Licence Agreement dated January 4, 2021 between Ascendis Pharma Bone Diseases A/S and VISEN Pharmaceuticals (PTH).	20-F	3/10/2021	4.20	001-36815	
4.16*	Revenue Participation Right Purchase and Sale Agreement dated September 5, 2023 between Ascendis Pharma Endocrinology Division A/S, Ascendis Pharma A/S and Royalty Pharma Development Funding, LLC.	20-F	2/7/2024	4.22	001-36815	
4.17*	Revenue Participation Right Purchase and Sale Agreement dated September 3, 2024 between Ascendis Pharma Bone Diseases A/S, Ascendis Pharma A/S and Royalty Pharma Development Funding LLC.	20-F	2/12/2025	4.23	001-36815	
4.18*	Supply Agreement dated October 1, 2022 between Ascendis Pharma A/S and Vetter Pharma International GmbH.	20-F	2/12/2025	4.24	001-36815	
4.19*	Amendment Number 1 to Supply Agreement dated April 8, 2024 between Ascendis Pharma A/S and Vetter Pharma International GmbH	20-F	2/12/2025	4.25	001-36815	
4.20	Ascendis Pharma A/S Restricted Stock Unit Program.	S-8	2/27/2025	99.1	333-285322	
4.21	Ascendis Pharma A/S Performance Stock Unit Program.	S-8	2/27/2025	99.2	333-285322	
8.1	List of Subsidiaries.					X
11.1	Insider Trading Compliance Policy.					X

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	Date	Number	File Number	
12.1	Certification by Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
12.2	Certification by Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
13.1	Certification by Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
13.2	Certification by Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
15.1	Consent of Independent Registered Public Accounting Firm.					X
97.1	Ascendis Pharma A/S Policy for Recovery of Erroneously Awarded Compensation.	20-F	2/7/2024	97.1	001-36815	
EX-101.INS	Inline XBRL Instance Document.					X
EX-101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.					X
104	Cover page interactive data file (formatted as Inline XBRL and included in Exhibit 101).					X

† Confidential treatment has been granted for certain information contained in this Exhibit. Such information has been omitted and filed separately with the SEC.

* Portions of this exhibit, marked by asterisks, have been omitted pursuant to Instruction 4(a) to Exhibits to Form 20-F because they are both (i) not material, and (ii) include information of the type that we treat as private or confidential.

Signatures

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Ascendis Pharma A/S

/s/ Jan Møller Mikkelsen

By: Jan Møller Mikkelsen
President, Chief Executive Officer and Board Member
(Principal Executive Officer)

Date: February 11, 2026

/s/ Scott T. Smith

By: Scott T. Smith
Executive Vice President, Chief Financial Officer
(Principal Financial Officer)

Date: February 11, 2026

Exhibit 2.3

DESCRIPTION OF SHARE CAPITAL

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

General

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

Authorizations to our board of directors

As of December 31, 2025, 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 nominal DKK 9,000,000 with pre-emptive subscription rights for existing shareholders. Capital increases according to this authorization shall be carried out by our board of directors by way of cash contributions. This authorization is valid until May 29, 2029.
- Our board of directors is authorized to increase our share capital by up to nominal DKK 3,825,000 without pre-emptive subscription rights for existing shareholders. Capital increases according to this authorization can be carried out by our board of directors by way of contributions in kind, conversion of debt and/or cash contributions, and must be carried out at market price as determined in accordance with Danish law. This authorization is valid until May 27, 2030.
- Our board of directors is authorized to issue 100,000 warrants to new members of the board of directors of the Company or its subsidiaries in connection with their first election and to increase our share capital by up to 100,000 shares without pre-emptive rights for existing shareholders in connection with the exercise, if any, of said warrants. The warrants issued shall be governed by the terms and conditions set out in appendix 1a to our articles of association. The exercise price for the warrants shall be determined by the board of directors in consultation with the Company's advisors and shall at least be equal to the market price of the shares at the time of issuance as determined in accordance with Danish law. No single board member shall receive more than 10,000 warrants pursuant to the authorization. This authorization is valid until May 27, 2030.

- Our board of directors is authorized to obtain loans against issuance of convertible bonds which confer the right to subscribe for shares in the Company. The Company's existing shareholders shall not have pre-emption rights to such shares. Our board of directors is authorized to increase the share capital by up to nominal DKK 9,000,000 by conversion of the convertible bonds. The convertible bonds shall be offered at a subscription price and a conversion price that correspond in aggregate to at least the market price of the shares at the time of the decision of our board of directors to issue the convertible bonds as determined in accordance with Danish law. The loans shall be paid in cash and our board of directors shall determine the terms and conditions for the convertible bonds. This authorization is valid until May 29, 2027.
- Our board of directors is authorized to issue 625,233 warrants to members of the executive management and employees, advisors and consultants of the Company or our subsidiaries and to increase our share capital by up to 625,233 shares, without pre-emptive subscription rights for existing shareholders in connection with the exercise, if any, of said warrants and to determine the terms and conditions thereof. The exercise price for the warrants shall be determined by the board of directors in consultation with the Company's advisors and shall at least be equal to the market price of the shares at the time of issuance as determined in accordance with Danish law. This authorization is valid until May 29, 2027.
- Our board of directors is authorized to issue 1,000,000 warrants to members of the executive management and employees, advisors and consultants of the Company or our subsidiaries and to increase our share capital by up to 1,000,000 shares, without pre-emptive subscription rights for existing shareholders in connection with the exercise, if any, of said warrants and to determine the terms and conditions thereof. The exercise price for the warrants shall be determined by the board of directors in consultation with the Company's advisors and shall at least be equal to the market price of the shares at the time of issuance as determined in accordance with Danish law. This authorization is valid until May 29, 2029.
- If our board of directors exercises its authorizations in full, and all warrants and convertible debt instruments are exercised fully (not including already issued warrants and already issued convertible debt instruments), then our share capital will amount to 85,527,641 shares consisting of 85,527,641 shares with a nominal value of DKK 1 each.

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

Our warrants

Our employees, consultants, advisors and board members are eligible to participate in our warrant incentive program. Warrants have been issued by the general meeting or by our board of directors pursuant to valid authorizations in our articles of association and the terms and conditions have, in accordance with the Danish Companies Act, been incorporated in our articles of association as in effect from time to time. Each warrant grants the holder the right to subscribe for one ordinary share against cash payment of the exercise price. The exercise price is determined by our board of directors and historically has not been less than the estimated fair value of our ordinary shares on the date of grant. As of December 31, 2025, our board of directors is authorized to issue 1,755,233 warrants in the period ending May 27, 2030. As of December 31, 2025, there were outstanding 5,222,591 warrants to subscribe for our ordinary shares and such warrants had a weighted-average exercise price of €103.24.

The grant of warrants to any participant is at the discretion of our board of directors and based on the recommendation of our management. The board of directors may determine the terms and conditions of the warrants issued, including exercise periods, subscription price and adjustments caused by changes to our company's situation. Warrantholders are entitled to an adjustment of the number of warrants issued and/or the exercise price applicable in the event of certain corporate changes. Events giving rise to an adjustment include, among other things, increases or decreases to our share capital at a price below or above market value, respectively, the issuance of bonus shares, changes in the nominal value of each share and payment of dividends in excess of 10% of our company's equity. For the purpose of implementing the capital increases necessary in connection with the exercise of warrants, our board of directors has been authorized to increase our share capital by one or more issuances of shares with a total nominal value corresponding to the number of warrants issued upon cash payment of the exercise price without any pre-emptive subscription rights to existing shareholders.

Subject to earlier vesting upon the occurrence of certain exit events, warrants granted under the program from December 2012 until and including November 2021 generally vest 1/48th per month from the date of grant subject to continued service for employees, consultants and grants to board members. However, effective from December 2015, subsequent grants to board members vest 1/24th per month from the date of grant. With respect to employees, in the event that a holder resigns due to our breach of employment terms or we terminate the employment relationship and the holder has not given us good reason to do so, the warrants will continue to vest post-termination in accordance with the same vesting schedule. Otherwise, warrants will cease vesting upon termination of service with respect to employees, board members and consultants.

Subject to earlier vesting, upon the occurrence of certain exit events, for warrants granted under the program as in effect since December 9, 2021, the following vesting applies:

25% of the warrants granted to employees and consultants generally vest one year after the time of grant, and the remaining 75% of the warrants granted generally vest with 1/36 per month from one year after the time of grant. As regards warrants which board members are granted in connection with appointment, 25% of the warrants granted generally vest one year after the time of the grant (the initial grant after the board member's accession), and the remaining 75% of the warrants granted generally vest with 1/36 per month from one year after the time of the grant. Regarding any subsequent grants of warrants to board members ("Subsequent Warrants"), 50% of the Subsequent Warrants generally vest one year after the time of such subsequent grant and the remaining 50% of the Subsequent Warrants shall generally vest with 1/12 per month from one year after the time of such subsequent grant. Warrants will generally cease vesting upon termination of service with respect to employees, consultants and board members.

Vested warrants may be exercised during certain exercise periods each year. For outstanding warrants, there are four annual exercise periods; each exercise period begins two full trading days after the publication of the public release of our earnings data of a fiscal quarter and continues until the end of the second-to-last trading day in which quarter the relevant earnings release is published. The warrants expire ten years after the grant date.

RSU and PSU program

Our board of directors has received authorization from stockholders during the period until May 27, 2026 to purchase up to 2,000,000 shares or ADSs representing a corresponding amount of shares in the company as treasury shares. In addition, our board of directors has received authorization from stockholders during the period until May 29, 2028 to purchase up to additional 1,000,000 shares or ADSs representing a corresponding amount of shares in the company as treasury shares.

Our board of directors has partially exercised this right and the company re-purchased 154,837 ADSs in November 2021, 1,000,000 ADSs in March 2022 and 119,148 ADSs in March 2025, representing a corresponding amount of shares in the company as treasury shares primarily for grants of Restricted Stock Units ("RSUs") and/or Performance Stock Units ("PSUs") in connection with the implementation of a Restricted Stock Units Program ("RSU Program") and a Performance Stock Units program ("PSU Program"). Since 2022, 676,889 ADSs were transferred to holders under the Company's RSU and PSU Programs.

RSU Program

RSUs may be granted to members of the senior management team, non-executive directors, and other employees ("RSU Participants") employed with the company or another company within the company's group. Our board of directors may also, at its sole discretion, decide to grant RSUs to consultants or members of our board of directors who are then also deemed RSU Participants.

One RSU represents a right for the RSU Participant to receive one ADS upon vesting. ADSs underlying RSUs are deemed to be treasury shares that have been repurchased in the market and, upon vesting, the company may at its sole discretion choose to make a cash settlement instead of delivering ADSs.

Our board of directors may, in its sole discretion, at any given point in time, decide to grant RSUs and may at its discretion and on an individual basis decide to deviate from the vesting principles and/or the vesting conditions as set forth in the RSU Program.

RSUs are granted to the RSU Participant free of charge. It is a condition for vesting that the RSU Participant is still either employed or retained as consultant within the company or another company within the company's group or serving as member of the board of directors on the vesting date. Subject to earlier vesting, upon the occurrence of certain exit events, for each award of RSUs, 1/3 of such RSUs will vest on each anniversary of the date of grant, subject to continued service.

In March 2025, our board of directors granted an aggregate of (i) 15,520 RSUs to certain non-employee board members of the company, (ii) 122,915 RSUs to certain members of senior management of the company, and (iii) 496,154 RSUs to certain other employees of the company under the terms of the RSU Program.

PSU Program

PSUs may be granted to members of the senior management team, non-executive directors and other employees ("PSU Participants") employed with the company or another company within the company's group. Our board of directors may also at its sole discretion decide to grant PSUs to consultants or members of our board of directors, who are then also deemed PSU Participants.

One PSU represents a right for the PSU Participant to receive one ADS upon vesting. ADSs underlying PSUs are deemed to be treasury shares that have been repurchased in the market and, upon vesting, the company may at its sole discretion choose to make a cash settlement instead of delivering ADSs.

Our board of directors may, in its sole discretion, at any given point in time, decide to grant PSUs and may at its discretion and on an individual basis decide to deviate from the vesting principles and/or the vesting conditions as set forth in the company's PSU Program.

PSUs are granted to the PSU Participant free of charge. It is a condition for vesting that the PSU Participant is still either employed or retained as consultant within the company or another company within the company's group or serving as member of the board of directors on the vesting date. Subject to earlier vesting, upon the occurrence of certain exit events, for each award of PSUs 1/3 of such PSUs will vest on each anniversary of the date of grant, subject to continued service and subject to the fulfillment of the performance conditions as determined by our board of directors.

All PSUs and any rights or payments in respect thereto will be subject to recoupment by the company to the extent required to comply with applicable law or any policy of the company providing for the reimbursement of incentive compensation.

In March 2025, our board of directors granted an aggregate of 73,583 PSUs to certain members of senior management of the company under the terms of the PSU Program.

Registration rights

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

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

Expenses of registration

Under the 2015 Registration Rights Agreement, we agreed to pay certain registration expenses of the holders of the shares registered pursuant to the registration rights described above, excluding, among other things, the expenses of

counsel for Fidelity Securities Fund: Fidelity Series Small Cap Opportunities Fund—Healthcare Sub and Fidelity Stock Selector Small Cap Fund—Health Care Sub.

Expiration of registration rights

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

Owners' register

We are obligated to maintain an owners' register (in Danish: *ejerbog*). The owners' register is maintained by Computershare A/S (Company Registration (CVR) no. 27088899), our Danish share registrar. It is mandatory that the owners' register is maintained within the European Union and that it is available to public authorities. Pursuant to the Danish Companies Act, public and private limited liability companies are required to register with the Danish Business Authority information regarding shareholders who own at least 5% of the share capital or the voting rights. Pursuant to this provision, we file registrations with the Public Owners' Register of the Danish Business Authority. Shareholders that exceed the ownership threshold must notify us and we will subsequently file the information with the Danish Business Authority. Reporting is further required when thresholds of 5%, 10%, 15%, 20%, 25%, 50%, 90% or 100%, or 1/3 or 2/3 are reached or no longer reached.

Articles of association and Danish corporate law

With respect to our articles of association, the following should be emphasized:

Objects clause

Our corporate object, as set out in article 3 of our articles of association, is to develop ideas and preparations for the combating of disease medically, to manufacture and sell such preparations or ideas, to own shares of companies with the same objects and to perform activities in natural connection with these objects.

Summary of provisions regarding the board of directors and the executive board

Pursuant to our articles of association, our board of directors shall be elected by our shareholders at the general meeting and shall be composed of not less than three and no more than 10 members. The members of the board of directors are elected for a term expiring at the first coming annual general meeting following their election. Board members must retire from the board of directors at the annual general meeting following their 75th birthday. Board members are not required to own any shares of our share capital.

The board of directors shall appoint and employ an executive board consisting of one to five members to attend to our day-to-day management, and the board of directors shall determine the terms and conditions of the employment.

Voting rights

Each shareholder is entitled to one vote for each share owned at the time of any general meeting. As compared with Danish citizens, there are no limitations under the articles of association or under Danish law on the rights of foreigners or non-Danish citizens to hold or vote our shares.

Dividend rights

Our shareholders may at general meetings authorize the distribution of ordinary and extraordinary dividends. Our shareholders may not distribute dividends in excess of the recommendation from our board of directors and may only pay out dividends from our distributable reserves, which are defined as results from operations carried forward and reserves that are not bound by law after deduction of loss carried forward.

Our shareholders are eligible to receive any dividends declared and paid out. However, we have not to date declared or paid any dividends and we currently intend to retain all available financial resources and any earnings generated by our operations for use in the business and we do not anticipate paying any dividends in the foreseeable future. The payment of any dividends in the future will depend on a number of factors, including our future earnings, capital requirements, financial condition and future prospects, applicable restrictions on the payment of dividends under Danish law and other factors that our board of directors may consider relevant.

See the section titled "*Item 10 E. Additional Information—Taxation*" in our Annual Report on Form 20-F for a summary of certain tax consequences in respect of dividends or distributions to holders of our ordinary shares or the ADSs.

Pre-emptive subscription rights

Under Danish law, all shareholders have pre-emptive subscription rights in connection with capital increases that are carried out as cash contributions. An increase in share capital can be resolved by the shareholders at a general meeting or by the board of directors pursuant to an authorization given by the shareholders. In connection with an increase of a company's share capital, the shareholders may, by resolution at a general meeting, approve deviations from the general Danish pre-emptive rights of the shareholders. Under the Danish Companies Act, such resolution must be adopted by the affirmative vote of shareholders holding at least a two-thirds majority of the votes cast and the share capital represented at the general meeting.

The board of directors may resolve to increase our share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations set forth above under the caption "Authorizations to our board of directors."

Unless future issuances of new shares and/or pre-emptive rights are registered under the Securities Act or with any authority outside Denmark, U.S. shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights.

Rights on liquidation

Upon a liquidation or winding-up of our company, shareholders will be entitled to participate, in proportion to their respective shareholdings, in any surplus assets remaining after payment of our creditors.

Limitations on holding of shares

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

Liability to capital calls by us

Under our articles of association as well as the Danish Companies Act, our shareholders are not obligated to pay further amounts to us. All our shares are fully paid.

Sinking fund provisions

There are no sinking fund provisions or similar obligations relating to our ordinary shares.

Disclosure requirements

Pursuant to Section 55 of the Danish Companies Act, a shareholder is required to notify us when such shareholder's stake represents 5% or more of the voting rights in our company or the nominal value accounts for 5% or more of the share capital, and when a change of a holding already notified entails that the limits of 5%, 10%, 15%, 20%, 25%, 50%, 90% or 100%, or 1/3 or 2/3 are reached or no longer reached. The notification shall be given within two weeks following the date when the limits are reached or are no longer reached.

The notification must include information on the date of acquisition or disposal of the shares, the number and, if applicable, the share class, the full name, address and civil registration ("CPR") number of the shareholder or the name, central business register ("CVR") number and registered office of the enterprise. If the shareholder has no CPR number or CVR number, such notice must be accompanied by other documentation securing unambiguous identification of the shareholder. The notice must also include information on the denomination or nominal value of the shares and the voting rights attaching to the shares.

Pursuant to section 58a, we are obligated to collect and store for a period of at least five years certain information regarding the beneficial owners of shares in the company. A beneficial owner is a physical person who ultimately holds or controls, directly or indirectly, a sufficient part of the ownership interests or voting rights or exercises control by other means, except for owners of companies whose ownership interests are traded on a regulated market or a similar market which is subject to a duty of disclosure in accordance with EU law or similar international standards.

The legal status of the notification obligations is not fully clarified in relation to ADS holders and an ADS holder may be subject to such obligations.

General meetings

The general meeting of shareholders is the highest authority in all matters, subject to the limitations provided by Danish law and the articles of association. The annual general meeting shall be held in the Greater Copenhagen area not later than the end of May in each year.

At the annual general meeting, the audited annual report is submitted for approval, together with the proposed appropriation of profit/treatment of loss, the election of the board of directors and election of our auditors. In addition, the board of directors reports on our activities during the past year.

General meetings are convened by the board of directors with a minimum of two weeks' notice and a maximum of four weeks' notice. A convening notice will be forwarded to shareholders recorded in our owners' register, who have requested such notification and by publication in the Danish Business Authority's computerized information system and on the company's website.

At the latest, two weeks before a general meeting (inclusive of the day of the general meeting), we shall make the following information and documents available on our webpage:

- the convening notice,
- the documents that shall be presented at the general meeting, which will, in the case of the annual general meeting, include the annual report, and
- the agenda and the complete proposals.

Shareholders are entitled to attend general meetings, either in person or by proxy, and they or their proxy may be accompanied by one advisor. A shareholder's right to attend general meetings and to vote at general meetings is determined on the basis of the shares that the shareholder holds on the registration date. The registration date shall be one week before the general meeting is held. The shares which the individual shareholder holds are calculated on the registration date on the basis of the registration of ownership in the owners' register as well as notifications concerning ownership which the company has received with a view to update the ownership in the owners' register. In addition, any shareholder who is entitled to attend a general meeting and who wishes to attend must have requested an admission card from us no later than three days in advance of the general meeting. Any shareholder is entitled to submit proposals to be discussed at the general meetings. However, proposals by the shareholders to be considered at the annual general meeting must be submitted in writing to the board of directors not later than six weeks before the annual general meeting.

Extraordinary general meetings must be held upon resolution of an annual general meeting to hold such a meeting or upon request of the board of directors, our auditors or shareholders representing at least 1/20 of the registered share capital or such lower percentage as our articles of association may provide. Our articles of association do not state such lower percentage.

Holders of ADSs are not entitled to directly receive notices or other materials or to attend or vote at general meetings.

Resolutions in general meetings

Resolutions made by the general meeting generally may be adopted by a simple majority of the votes cast, subject only to the mandatory provisions of the Danish Companies Act and our articles of association. Resolutions concerning all amendments to the articles of association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder's ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose or increase any obligations of the shareholders towards the company require unanimity.

Quorum requirements

There are no quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares.

Squeeze out

According to Section 70 of the Danish Companies Act, shares in a company may be redeemed by a shareholder holding more than nine-tenths of the shares and the corresponding voting rights in the company. Furthermore, according to Section 73 of the Danish Companies Act, a minority shareholder may require a majority shareholder holding more than nine-tenths of the shares and the corresponding voting rights to redeem the minority shareholder's shares.

Danish rules intended to prevent market abuse

As of July 3, 2016, EU Regulation No 596/2014 on market abuse entered into force and Chapter 10 of the Danish Securities Trading Act was repealed. Pursuant to said Chapter 10, we had adopted an internal code on inside information in respect of the holding of and carrying out of transactions by our board of directors and executive officers and employees in the shares or ADSs or in financial instruments the value of which is determined by the value of the ordinary shares or ADSs, and we had drawn up a list of those persons working for us who could have access to inside information on a regular or incidental basis and had informed such persons of the rules on insider trading and market manipulation, including the sanctions which could be imposed in the event of a violation of those rules. However, said EU Regulation No 596/2014 on market abuse imposes no such requirements on us and we have abandoned our previous practice.

Limitation on liability

Under Danish law, members of the board of directors or senior management may be held liable for damages in the event that loss is caused due to their negligence. They may be held jointly and severally liable for damages to the company, the shareholders and to third parties for acting in violation of the articles of association and Danish law.

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

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

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

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

Comparison of Danish corporate law and our articles of association and Delaware corporate law

The following comparison between Danish corporate law, which applies to us, and Delaware corporate law, the law under which many publicly traded companies in the United States are incorporated, discusses additional matters not otherwise described in our Annual Report on Form 20-F. This summary is subject to Danish law, including the Danish Companies Act, and Delaware corporate law, including the Delaware General Corporation Law. Further, please note that ADS holders will not be treated as our shareholders and will not have any shareholder rights.

Duties of board members

Denmark. Public limited liability companies in Denmark are usually subject to a two-tier governance structure with the board of directors having the ultimate responsibility for the overall supervision and strategic management of the company in question and with an executive board/management being responsible for the day-to-day operations. Each board member and member of the executive board/management is under a fiduciary duty to act in the interest of the company, but shall also take into account the interests of the creditors and the shareholders. Under Danish law, the members of the board of directors and executive management of a limited liability company are liable for losses caused by negligence whether shareholders, creditors or the company itself suffers such losses. They may also be liable for wrongful information given in the annual financial statements or any other public announcements from the company. An investor suing for damages is required to prove its claim with regard to negligence, loss, and causation. Danish courts, when assessing negligence, have been reluctant to impose liability unless the directors and officers neglected clear and specific duties. This is also the case when it comes to liability with regard to public offerings or liability with regard to any other public information issued by the company.

Delaware. The board of directors bears the ultimate responsibility for managing the business and affairs of a corporation. In discharging this function, directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. Delaware courts have decided that the directors of a Delaware corporation are required to exercise informed business judgment in the performance of their duties. Informed business judgment means that the directors have informed themselves of all material information reasonably available to them. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

Terms of the members of our board of directors

Denmark. Under Danish law, the members of the board of directors of a limited liability company are generally appointed for an individual term of one year. There is no limit on the number of consecutive terms the board members may serve. Pursuant to our articles of association, our board members are appointed by the general meeting of shareholders for a term of 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 dismiss a board member by a simple majority vote.

It follows from Section 140 of the Danish Companies Act that in limited liability companies that have employed an average of at least 35 employees in the preceding three years, the employees are entitled to elect a minimum of two representatives and alternate members to the company's board of directors up to one half the number of the shareholder elected directors. If the number of representatives to be elected by the employees is not a whole number, such number must be rounded up.

Our company currently employs more than an average of 35 employees and has done so since 2016. Consequently, from 2018, our employees have been entitled to demand representation on our board of directors. The question will, upon request from the employees, be put to a popular vote among the employees. If more than half of the employees (regardless of whether they participate in the vote) vote in favor of having representation, we must organize an election process.

Additionally, Section 141 of the Danish Companies Act allows for group representation on the board of directors of our company, i.e., that employees of our Danish subsidiaries may demand representation on our board. However, our Danish subsidiaries do not currently have employees. The employees of Ascendis Pharma, Inc., Ascendis Pharma Endocrinology, Inc., Ascendis Pharma GmbH, and Ascendis Pharma Endocrinology GmbH may only demand representation on our board of directors provided that our general meeting adopts a resolution to that effect.

Delaware. The Delaware General Corporation Law generally provides for a one-year term for directors, but permits directorships to be divided into up to three classes, of relatively equal size, with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the stockholders. A director elected to serve a term on a "classified" board may not be removed by stockholders without cause. There is no limit in the number of terms a director may serve.

Board member vacancies

Denmark. Under Danish law, in the event of a vacancy, new board members are elected by the shareholders in a general meeting. Thus, a general meeting will have to be convened to fill a vacancy on the board of directors. However, the board of directors may choose to wait to fill vacancies until the next annual general meeting of the company, provided that the remaining board members can still constitute a quorum. It is only a statutory requirement to convene a general meeting to fill vacancies if the number of remaining members on the board is less than three.

Delaware. The Delaware General Corporation Law provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (1) otherwise provided in the certificate of incorporation or bylaws of the corporation or (2) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Conflict-of-interest transactions

Denmark. Under Danish law, board members may not take part in any matter or decision-making that involves a subject or transaction in relation to which the board member has a conflict of interest with us.

Delaware. The Delaware General Corporation Law generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- the material facts as to the director's relationship or interest are disclosed and a majority of disinterested directors' consent;
- the material facts are disclosed as to the director's relationship or interest and a majority of shares entitled to vote thereon consent; or
- the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the stockholders.

Proxy voting by board members

Denmark. In the event that a board member in a Danish limited liability company is unable to participate in a board meeting, the elected alternate, if any, shall be given access to participate in the board meeting. Unless the board of directors has decided otherwise, or as otherwise is set out in the articles of association, the board member in question may in special cases grant a power of attorney to another board member, provided that this is considered safe considering the agenda in question.

Delaware. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Shareholder rights

Notice of meeting

Denmark. According to the Danish Companies Act, general meetings in limited liability companies shall be convened by the board of directors with a minimum of two weeks' notice and a maximum of four weeks' notice as set forth in the articles of association. A convening notice shall be forwarded to shareholders recorded in the company's 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 the company or its subsidiaries do not confer the right to vote.

Delaware. Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event can a quorum consist of less than one third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than ten days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

Shareholder proposals

Denmark. According to the Danish Companies Act, extraordinary general meetings of shareholders will be held whenever the board of directors or the 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 made in writing and forwarded at the latest six weeks prior thereto. In the event that the proposal is received at a later date, the board of directors will decide whether the proposal has been forwarded in due time to be included on the agenda.

Delaware. Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting of stockholders. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least $2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

Action by written consent

Denmark. Under Danish law, it is permissible for shareholders to take action and pass resolutions by written consent in the event of unanimity; however, this will normally not be the case in listed companies and for a listed company, this method of adopting resolutions is generally not feasible.

Delaware. Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

Appraisal rights

Denmark. The concept of appraisal rights does not exist under Danish law, except in connection with statutory redemptions rights according to the Danish Companies Act.

According to Section 73 of the Danish Companies Act, a minority shareholder may require a majority shareholder that holds more than 90% of the company's registered share capital and votes to redeem his or her shares. Similarly, a majority shareholder holding more than 90% of the company's share capital and votes may, according to Section 70 of the same act, squeeze out the minority shareholders. In the event that the parties cannot agree to the redemption squeeze out price, this shall be determined by an independent evaluator appointed by the court. Additionally, there are specific regulations in Sections 249, 267, 285 and 305 of the Danish Companies Act that require compensation in the event of national or cross-border mergers and demergers. Moreover, shareholders who vote against a cross-border merger or demerger or cross-border conversion are, according to Sections 286, 306 and 318 m of the Danish Companies Act, entitled to have their shares redeemed.

Delaware. The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

Shareholder suits

Denmark. Under Danish law, only a company itself can bring a civil action against a third party; an individual shareholder does not have the right to bring an action on behalf of a company. An individual shareholder may, in its own name, have an individual right to take action against such third party in the event that the cause for the liability of that third party also constitutes a negligent act directly against such individual shareholder.

Delaware. Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

Repurchase of shares

Denmark. Danish limited liability companies may not subscribe for newly issued shares in their own capital. Such company may, however, according to the Danish Companies Act Sections 196-201, acquire fully paid shares of its own capital, provided that the board of directors has been authorized thereto by the shareholders acting in a general meeting. Such authorization can only be given for a maximum period of five years and the authorization shall fix (i) the maximum value of the shares and (ii) the minimum and the highest amount that the company may pay for the shares. Shares may generally only be acquired using distributable reserves.

Delaware. Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

Anti-takeover provisions

Denmark. Under Danish law, it is possible to implement limited protective anti-takeover measures. Such provisions may include, among other things, (i) different share classes with different voting rights, (ii) specific requirements to register the shares named in the company's owners register and (iii) notification requirements concerning participation in general meetings. We have currently not adopted any such provisions.

Delaware. In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits "business combinations," including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation's voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transaction;
- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or
- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until 12 months following its adoption.

Inspection of books and records

Denmark. According to Section 150 of the Danish Companies Act, a shareholder may request an inspection of the company's books regarding specific issues concerning the management of the company or specific annual reports. If approved by shareholders with simple majority, one or more investigators are elected. If the proposal is not approved by simple majority but 25% of the share capital votes in favor, then the shareholder can request the court to appoint an investigator.

Delaware. Under the Delaware General Corporation Law, any stockholder may inspect certain of the corporation's books and records, for any proper purpose, during the corporation's usual hours of business.

Pre-emptive rights

Denmark. Under Danish law, all shareholders have pre-emptive subscription rights in connection with capital increases that are carried out as cash contributions. In connection with an increase of a company's share capital, the shareholders may, by resolution at a general meeting, approve deviations from the general Danish pre-emptive rights of the shareholders. Under the Danish Companies Act, such resolution must be adopted by the affirmative vote of shareholders holding at least a two-thirds majority of the votes cast and the share capital represented at the general meeting. The board of directors may resolve to increase our share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations described above under the caption "Authorizations to our board of directors." Unless future issuances of new shares are registered under the Securities Act or with any authority outside Denmark, U.S. shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights.

Delaware. Under the Delaware General Corporation Law, stockholders have no pre-emptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

Dividends

Denmark. Under Danish law, the distribution of ordinary and extraordinary dividends requires the approval of a company's shareholders at a company's general meeting. Under the Danish Companies Act the general meeting may authorise the board of directors to resolve to distribute extraordinary dividends after presentation of a company's first financial statements. The authorisation may be subject to financial and time restrictions. 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. The decision to pay out extraordinary 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 extraordinary dividend payment shall be prepared.

If a resolution to distribute extraordinary dividends is passed more than six months after the balance sheet date as set out in the company's latest approved annual report an interim balance sheet showing that sufficient funds are available for distribution must 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, demergers with the company as the transferor company and demergers with the company as the existing transferee if amendment of the articles of association for any purpose other than the adoption of the transferor company's name or secondary name as the transferee company's secondary name is required to be made. Under Danish law, it is debatable whether the shareholders must approve a decision to sell all or virtually all of the company's business/assets.

Delaware. Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

However, under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, unless required by the certificate of incorporation, if (1) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (2) the shares of stock of the surviving corporation are not changed in the merger and (3) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

Amendments to governing documents

Denmark. All resolutions made by the general meeting may be adopted by a simple majority of the votes, subject only to the mandatory provisions of the Danish Companies Act and the articles of association. Resolutions concerning all amendments to the articles of association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder's ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose any or increase any obligations of the shareholders towards the company require unanimity.

Delaware. Under the Delaware General Corporation Law, a corporation's certificate of incorporation may be amended only if adopted and declared advisable by the board of directors and approved by a majority of the outstanding shares entitled to vote (subject to limited exceptions), and the bylaws may be amended with the approval of a majority of the outstanding shares entitled to vote and may, if so provided in the certificate of incorporation, also be amended by the board of directors.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

Depositary

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

American Depositary Shares

The Bank of New York Mellon, as depositary, registers and delivers the ADSs. Each ADS represents one ordinary share (or a right to receive one ordinary share) deposited with The Bank of New York Mellon, acting through an office located in the United Kingdom, or any successor, as custodian for the depositary. Each ADS also represents any other securities, cash or other property which may be held by the depositary in respect of the depositary facility.

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

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

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

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

Dividends and Other Distributions

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

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

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

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

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

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

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

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

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

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

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

Deposit, Withdrawal and Cancellation

How are ADSs issued?

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

How can ADS holders withdraw the deposited securities?

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

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

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

Voting Rights

How do you vote?

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

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

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

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote ordinary shares represented by your ADS. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions provided that any such failure is in good faith. This means that you may not be able to exercise your right to vote and there may be nothing you can do if ordinary shares represented by your ADSs are not voted as you requested.

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we will try to give the depositary notice of any such meeting and details concerning the matters to be voted upon sufficiently in advance of the meeting date.
Except as described above, you will not be able to exercise your right to vote unless you withdraw the ordinary shares. However, you may not know about the shareholder meeting far enough in advance to withdraw the ordinary shares.

Fees and Expenses

What fees and expenses will you be responsible for paying?

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

Persons depositing or withdrawing ordinary shares or ADSs must pay:	***For:***
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	• Issue of ADSs, including issues resulting from a distribution of ordinary shares or rights or other property

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

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

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

Payment of Taxes

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

Reclassifications, Recapitalizations and Mergers

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

Amendment and Termination

How may the deposit agreement be amended?

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

How may the deposit agreement be terminated?

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

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

Limitations on Obligations and Liability

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

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

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

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

Requirements for Depositary Actions

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

- payment of share transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any ordinary shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs generally when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Ordinary Shares Underlying Your ADSs

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

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

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

Direct Registration System

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

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

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

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

(NON-OFFICIAL ENGLISH TRANSLATION) **Exhibit 4.5**

CERTAIN IDENTIFIED CONFIDENTIAL INFORMATION HAS BEEN REDACTED FROM THIS EXHIBIT BECAUSE IT IS (I) CUSTOMARILY AND ACTUALLY TREATED AS PRIVATE OR CONFIDENTIAL AND (II) NOT MATERIAL.

CONFIDENTIAL PORTIONS OF THIS EXHIBIT ARE DESIGNATED BY [***].

Lease no.: 11-486-1007-6

COMMERCIAL LEASE CONTRACT

LANDLORD: Tuborg Havnevej I/S, CVR no.: 32 88 60 94

TENANT: Ascendis Pharma A/S, CVR no.: 29 91 87 91

THE PREMISES: Tuborg Boulevard 12, 2900 Hellerup

(NON-OFFICIAL ENGLISH TRANSLATION) **Exhibit 4.5**

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(NON-OFFICIAL ENGLISH TRANSLATION) **Exhibit 4.5**

LEASE AGREEMENT

Preamble

Since 1 July 2018 and 1 January 2019, respectively, the tenant has been the tenant of several leases in the property located Tuborg Boulevard 12, 2900 Hellerup. As of 15 January and 1 April 2025, the Tenant took over additional leases in the property, after which the leased premises will constitute the Premises, as stated in § 1.2 below.

This lease agreement thus covers the entire lease, although the lease may contain separate conditions that only concern either the original or new parts of the lease. In such cases, this will be specifically stated.

This lease agreement will enter into force on 1 July 2025, and replaces in its entirety the lease agreements previously entered into by the Tenant and the Landlord in the property.

§ 1.

The parties and the leased property

§ 1.1 Tuborg Havnevej I/S v/PKA Ejendomme, Dyregårdsvej 1, 2740 Skovlunde, (Landlord) hereby rents to

Ascendis Pharma A/S Tuborg Boulevard 12

2900 Hellerup

CVR no.: 29 91 87 91

(Tenant)

the following premises at Tuborg Boulevard 12, st. leases 6, 7 and 8, entire 1st floor, 2nd floor leases

15, 16 and 18, the entire 4th floor and basement leases 1 and 2, 2900 Hellerup in the property Tuborg Boulevard 12, matr. no. 5ac, Hellerup:

Lease	**Office m²**	**Share of canteen**	**Share of common above ground**	**Share of common sub-terrain**	**Total**
Basement Lease 1	[***]	[***]	[***]	[***]	[***]

Basement Lease 2	[***]	[***]	[***]	[***]	[***]
Stuen Lease 6	[***]	[***]	[***]	[***]	[***]
Stuen Tenancy 7	[***]	[***]	[***]	[***]	[***]
Stuen Lease 8	[***]	[***]	[***]	[***]	[***]
1st floor Lease 10-14	[***]	[***]	[***]	[***]	[***]
2nd floor lease 15	[***]	[***]	[***]	[***]	[***]
2nd floor lease 16	[***]	[***]	[***]	[***]	[***]
2nd floor lease 18	[***]	[***]	[***]	[***]	[***]
4th floor Lease 23-26	[***]	[***]	[***]	[***]	[***]
Total	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**

Parking spaces in the basement under the property Tuborg Boulevard 12	[***]	pcs.
Parking spaces in the basement under the property Tuborg Havnevej 15	[***]	pcs.
Parking spaces on terrain	[***]	pcs.
Parking spaces in total	**[***]**	**pcs.**

as shown in the drawing attached as Appendix 1 and with the extent inspected by the Tenant.

§ 1.2 The leases 2, 7-8, 10-14, 15 and 18 are collectively referred to in this lease as the Original Areas.

The leases 1, 6, 16, and 23-26 are collectively referred to in this lease as the New Areas.

§1.3 The calculation of the gross area is binding by the Landlord, and Land Ordinance No. 311 of 27 June 1983 does not apply, as long as it is not to the detriment of the tenant.

§1.4 The parking spaces are assigned in more detail by the Landlord, and are currently located cf. Appendix 6 (drawing), but the Landlord can move around the parking spaces in the basement with 1 month's notice.

§ 2.

Application

§ 2.1 The rented property must be used for office and administration and may not be used for any other purpose without the landlord's written consent. The lease may not be used for housing or night stays.

§ 2.2 The landlord guarantees that the use of the leased property for the above-specified business at the time of entry into force does not conflict with the local plan or other public planning.

§ 2.3 The Landlord bears neither responsibility nor risk for the Tenant's specific use of the Tenancy. The tenant is therefore responsible for ensuring that the agreed use is not covered by special public regulations and is obliged to obtain and maintain all permits required with regard to the layout and operation of the leased premises, including regulations relating to environmental and fire conditions. The landlord must be informed of the regulatory requirements without undue delay and receive a copy of the necessary permits.

§ 2.4 The tenant's use must not cause nuisance to odors, noise or light or in any other way be a nuisance to other tenants in the property or others. The tenant must ensure that their staff and others who have access to the rented property handle this responsibly.

§ 2.5 Changes to the rented property may only be made with the written approval of the Landlord. The tenant has the right, according to the landlord's reasonably justified instructions, to carry out installations and alterations when the changes are made in order to meet requirements from a public authority regarding contractual use of the rented property. The Landlord may require the Tenant, before a change is made, to pay a reasonable deposit in the Landlord's discretion as security for the restoration obligation. However, such a deposit is not only a security deposit for the aforementioned expenses, but also a security for any outstanding balance between the Tenant and the Landlord.

§ 2.6 The Renter is liable for any damage – including accidental damage – that is inflicted on the rented property or the property in general as a result of the Renter's installations, alterations or other disposal of the rented property.

§ 2.7 The Landlord is entitled to rent out or use other premises in the property for the same industry and the same use as the Tenant's.

§ 2.8 Signage, flags and other forms of advertising on and around the property as well as the establishment of awnings, sun shading and the like may only be carried out with the Landlord's prior written approval. The signage, etc., is established by the Tenant and at the Renter's expense, and it is the responsibility of the Tenant to meet all regulatory requirements and obtain regulatory approval.

§ 2.9 All costs in connection with the above measures are paid by the Renter, who is obliged to obtain all regulatory approvals himself and ensure that any conditions for the approval are constantly met.

§ 2.10 Upon moving out, the Tenant must, at his own expense, remove any traces of objects placed on the property in accordance with the above, including re-establishing facades, etc., unless the Landlord waives the requirement in writing.

§ 3.

Entry into force

§ 3.1 The Lease Agreement enters into force on 1 July 2025, and replaces previously entered into agreements between the Tenant and the Landlord on this date.

§ 3.2 When the Tenant's redevelopment of the Lease, cf. § 7.3, has been completed, which is expected to be in September 2025, a takeover transaction will be held for the New Areas, and the Landlord will prepare a move-in report including photos, which will be attached to the lease agreement as Appendix 3.2. The tenant notifies the landlord of the completion of the renovation and renovation, who then causes the parties to be summoned to a joint review of the lease with a view to preparing a move-in report.

§ 4.

Termination

§ 4.1 The lease is non-terminable from the Landlord's side until 1 July 2040, after which it can be terminated with 12 months' notice to end and move out on the 1st of a quarter.

§ 4.2 The lease is non-terminable from the Tenant's side until 1 July 2035, after which it can be terminated with 12 months' notice to end and move out on the 1st of a quarter.

§ 4.3 If the Tenant had to terminate the leased property earlier than 15 years after the date of entry into force, cf. § 3.1, the Tenant must pay to the Landlord a moving out penalty, cf. Appendix 8, corresponding to the remaining amount of the Landlord's investment in rebuilding and renovating the rented property. The amount is due in its entirety on the date of termination in such case. The landlord is entitled to offset his claim for payment of the moving out penalty against the deposit.

§ 4.4 The landlord has the right to place his own rental sign or equivalent on and in the façade of the tenancy during the notice period. During the same period, the Tenant is obligated – at the Landlord's request – to give potential future tenants access to an inspection of the tenancy.

§ 4.5 It has been specifically agreed that the Tenant is entitled to terminate the total leased area of

The 2nd floor or the 4th floor will cease no earlier than five (5) years after the entry into force of this part of the leased building, cf. section 3.1. Partial termination must be made with a minimum of 12 months' notice to end and move out on the 1st of a quarter.

§ 4.6 In the event of the Tenant's partial termination of the total area on the 2nd or 4th floor, cf. § 4.5, the Tenant must pay a move-out penalty to the Landlord, cf. Appendix 8, corresponding to the share of the remaining amount of the Landlord's investment in rebuilding and renovating this part of the rented

property at the time of termination. The amount is due in full on the date of cessation of the areas on the 2nd or

4th floor. The landlord is entitled to set off his claim for payment of the moving out penalty against the deposit.

§ 4.7 If the tenant exercises the right to partially terminate the areas on the 2nd or 4th floor, the distribution figures, all area-dependent services, cf. §§ 8-12 and the proportion of parking spaces shall be adjusted accordingly. The new distribution figures and parking spaces in the event of termination of the 2nd or

The 4th floor will then be as follows:

	Delopsays 2. sal	Delopsays 4. sal
Distribution figures §9	10.128,10	8.956,40
Distribution figures §10	8.862,00	7.776,50
Distribution figures §12	8.862,00	7.776,50
Parking spaces	77	68

§ 5.

Relinquishment and reinstatement

§ 5.1 The Tenant has the right to relinquish this lease unless the Landlord has justified objections to a new tenant's professional and financial circumstances or the Landlord otherwise has other weighty objections. Thus, the landlord is also entitled to refuse relinquishment if the incoming tenant's business may be in competition with other tenants in the Eden judgment.

§ 6.

Subletting

§ 6.1 The Tenant has the right to fully or partially sublet the lease for office activities to a legal person or a company if the Landlord cannot raise any justified objections against the person, including in relation to the person's professional and financial circumstances. Furthermore, the Landlord shall always be entitled to reject a potential subtenant if his business may be in competition with other tenants in the Property, however, not if this business corresponds to the Renter's own business. At the Landlord's request, the Tenant is obliged to send a copy of the sublease agreement to the Landlord. Subletting to companies or companies that are affiliated with the Tenant does not require the Landlord's consent. However, the Tenant must loyally inform the Landlord of this.

§ 7.

Handover of the rented property

§ 7.1 The Original Areas have been taken over, newly renovated, cf. drawing Appendix 1 and technical description Appendix 4a.

§ 7.2 The tenant carries out a rebuilding and renovation of the New Areas, so that these areas per Land Area. The date of entry into force is taken over newly renovated and as further described in Appendix 4b.

§ 7.3 The costs for rebuilding and renovating the leased premises as a result of the takeover of the New Areas are estimated at DKK [***] excluding VAT. The Landlord provides a contribution of DKK 10 million excl. VAT for the Tenant's rebuilding and renovation of the New Areas. It has been agreed that the Landlord will also finance a fixed amount of DKK 25,449,071 excluding VAT on the total renovation costs against the Renter's payment of a Rent Supplement, as defined and further described in section 8.2. The landlord's financing of the said amount is independent of whether the total renovation costs exceed the estimated amount. The Landlord's subsidy, DKK 10 million and financing DKK 25,449,071, will be paid to the Tenant when the Lease enters into force.

§ 8.

Annual benefits and deposit

§ 8.1 The annual rent is (incl. rent supplement) DKK **25.161.356,15**,- which appears as follows:

Ground floor, lease 6	[***]	[***]	[***]	[***]	[***]
Ground floor, lease 7	[***]	[***]	[***]	[***]	[***]
Ground floor, lease 8	[***]	[***]	[***]	[***]	[***]
Year 1	[***]	[***]	[***]	[***]	[***]
2nd floor lease 15	[***]	[***]	[***]	[***]	[***]
2nd floor lease 16	[***]	[***]	[***]	[***]	[***]
2nd floor lease 18	[***]	[***]	[***]	[***]	[***]
Year 4	[***]	[***]	[***]	[***]	[***]
Basement, warehouse lease 2	[***]	[***]	[***]	[***]	[***]
Basement, warehouse lease 1	[***]	[***]	[***]	[***]	[***]
Rent surcharge (see § 8.2)	[***]	[***]	[***]	[***]	[***]

Total	[***]	[***]	[***]	[***]	**[***]**
	[***]		[***]		[***]
106 parking spaces				per pitch	

§ 8.2 The Tenant is obliged to pay an annual additional rent corresponding to DKK [***] plus VAT (the "Rent Supplement"). The rent supplement is paid in addition to the annual rent in force at any given time as payment for the Landlord's financing of the conversion. A proportionate share of the Rental Supplement is collected and paid for the first time together with the rent for the Rental Measure. The Tenant must pay the Additional Rent for 15 years, after which payment of the Rent Supplement lapses.

Section 13 does not apply to the Rent Supplement.

If the Tenant vacates the lease, or the lease is otherwise terminated - regardless of the reason for this - within 15 years after the entry into force of the New Areas and the Tenant has thus not paid the Rent Supplement for 15 years, the Tenant is obliged to pay a penalty to the Landlord, cf. § 4 and Appendix 8. However, the Tenant is obliged to make payment immediately on the Landlord's request, if the Lease is vacated prematurely by the Tenant without due notice, or the Landlord as a result of the Tenant's breach of contract terminates the Lease.

In the event of partial termination of the areas located on the 2nd or 4th floor, a proportion of the Rent Supplement will be waived based on the size of the share of the terminated area in relation to the total leased area. The rental supplement amounts to DKK [***] per m2

Year 2	DKK [***]	[***]
4th floor	DKK [***]	[***]

The rent and the Rent Supplement are due for payment quarterly in advance each on 1 January, 1 April,

July 1 and October 1.

§ 8.3 The first payment of Rent and Rent Supplement for the total lease as specified in § 1 takes place as of the date of entry into force, where rent is paid for the period from the date of entry into force until the end of the quarter in question.

§ 8.4 In connection with the original lease agreements, the Tenant has paid a deposit of up to 6 months' rent for the Original Areas, corresponding to [***]. The Tenant has also made payment of the deposit in accordance with the previously applicable rent for the New Areas. No later than at the same time as the Tenant signs this lease, the Tenant is obliged to make payment to the Landlord of an additional deposit for the New Areas, so that the total security corresponds to 6 months' current rent, excluding the rent supplement for the total lease. The Landlord sends a separate charge to the Tenant on this.

§ 8.5 This deposit is guaranteed as security for any outstanding balance between the Tenant and the Landlord in connection with the tenancy, including as security for the Tenant's obligations in connection with moving out. The deposit is withheld until any outstanding balance between the parties has been settled.

§ 8.6 No interest is paid on the deposit. In the event of rent increases, the Landlord may require the Tenant to increase his deposit by cash payment, so that the total security at all times corresponds to 6 months' current rent, excluding the rent supplement.

§ 8.7 In addition to the rent, the Tenant pays a share of the expenses in accordance with the consumption accounts, cf. section 9**,** and a share of the expenses, cf. sections 10-12.

§ 8.8 All claims arising from this contract or the Commercial Lease Act are obligatory monetary payments.

§ 8.9 The tenant cannot refrain from paying rent or other services on the due date or make deductions from this, even if he may have a counterclaim against the landlord.

§ 9.

Consumption accounts (heat, water, etc.)

§ 9.1 The landlord ensures the supply of heating and hot water. The Renter is obliged to purchase all of his consumption of heating and hot water according to the Landlord's instructions, and the Renter pays for this in accordance with the guidelines below. The Tenant may not establish any other heat supply without the Landlord's written consent.

§ 9.2 The consumption accounts are prepared collectively for premises in the property or for units that have a common heat supply with it. The landlord may reduce or expand the units that have a common heat supply with the property and change the distribution among the units that participate in the joint heat supply.

§ 9.3 The consumption accounts include the expenses listed below, subject to the reservation for unknown and/or new expenses.

§ 9.4 For the financial year 2025, the expenses for the entire property are budgeted as follows

Property area:		18.615,90	
The lease's share:			12.370,50
Expenses:		**The property's share**	**Share of the lease**
District heating	Kr.	800.000	531.610
Energy management	Kr.	18.000	11.961
Energy labelling	Kr.	10.000	6.645

Repairs and maintenance of heating systems	Kr.	18.000	11.961
CTS	Kr.	138.000	91.703
Heating systems, deposits	Kr.	605.000	402.030
Fee	Kr.	26.000	17.277
Total excl. VAT	**kr.**	**1.615.000**	**1.073.188**

§ 9.5 The lease's share of the costs for heat consumption, energy labelling, etc. is estimated at DKK

1,073,188 p.a. excl. VAT.

§ 9.6 The costs of heat consumption shall be distributed among the tenants on the basis of distribution meters in the leases to the extent that they exist, and on the basis of criteria established by a heating engineer chosen by the Landlord, taking into account, among other things, the area and the room and male shares. All other expenses are distributed among the tenants in the property in proportion to the area of the individual lease in relation to the total area of the property at any given time, which is 18,615.90 m². However, expenses that can only be attributed to one or more of the individual leases in the property are distributed among these tenants in proportion to the gross areas involved. The lease's share is 12,370 m2 / 18,615.90 m², but can be changed, cf. § 1. The landlord is entitled to change the distribution key in the areas of the lease or property at any time and without notice, as long as it is not to the detriment of the tenant.

§ 9.7 If the Landlord deems that a Tenant's business will result in an increase beyond the usual in the costs of, for example, refuse collection or other expenses, the Landlord may impose a proportionately larger payment of the expenses in question on the Tenant and thus deviate from the otherwise applicable distribution principles.

§ 9.8 To cover the consumption expenses, the Tenant pays a quarterly advance contribution, which is deducted from the final calculated expense for the financial year in question. This contribution on account may be changed at any time and without notice so that it always covers the actual expenses.

§ 9.9 The final statement of the consumption accounts expenses is made once a year, as of 1 January-present. The landlord can reschedule the consumption accounting period with 2 weeks' written notice, and the rescheduling period may comprise more or less than 12 months.

§ 9.10 If, as a result of an error or oversight, the Landlord has omitted to include an expense item in the accounts or included it with an amount that is too small, the Landlord is entitled, regardless of the size thereof, to either transfer the omitted expense item or any difference to the following consumption accounts or to collect the amount when the error is found.

§ 9.11 The landlord is not responsible for temporary disturbances in the heating and hot water supply, but must remedy such disturbances as soon as possible.

§ 9.12 Even though the contract covers the supply of heating and hot water throughout the year, the Landlord may interrupt the hot water supply during the summer without compensation to the extent necessary for the purpose of inspection of the system, etc.

§ 9.13 If the Tenant objects to the consumption accounts, and the Landlord rejects them, the Tenant's objection is deemed to have lapsed, unless the Tenant within 2 weeks after receipt of the Landlord's rejection notifies the Landlord in writing that the objection is maintained and that the Tenant therefore wishes the case to be brought before the Housing Court.

§ 10.

Profit and loss account (operating and service expenses)

§ 10.1 In addition to the agreed rent and the expenses mentioned in §§ 9, 11 and 12, the Landlord is entitled to claim reimbursement of operating expenses relating to the property, which are listed below. Unless otherwise stated, the Landlord is responsible for all measures regarding the property costs in return for reimbursement of these, cf. below.

§ 10.2 The income statement includes the expenses listed below, subject to the reservation for unknown and/or new expenses.

§ 10.3 For the financial period 2025, the expenses for the entire property are budgeted as follows:

Condominium 1 above ground:		**12.679,70**	
The lease's share above ground:			**11.439,10**
Expenses:		**The property's share**	**The part of the lease**
Land tax	Kr.	984.755	888.406
Cover charge	Kr.	2.599.586	2.345.239
Rat control	Kr.	2.569	2.318
The property's area above ground:		**16.342,30**	
The lease's share above ground:			**11.439,10**
Expenses:		**The property's share**	**The lease's application of the**

Electricity for indoor and outdoor common areas	Kr.	500.000	349.984
Electricity tax	Kr.	400.000	279.988
Water for common areas incl. the canteen	Kr.	200.000	139.994
Caretaker	Kr.	710.000	496.978
Service subscription ventilation	Kr.	115.000	80.496
Service subscription automation on windows	Kr.	20.000	13.999
Service subscription revolving doors	Kr.	17.000	11.899
Cleaning of grease traps and wells	Kr.	17.000	11.899
Lifts - Statutory inspection and fall tests	Kr.	35.000	24.499
Service subscription elevators and alarm line	Kr.	8.000	5.600
Service subscription sprinkler	Kr.	20.000	13.999
Service subscription groundwater pumps	Kr.	5.000	3.500
Service subscription fire alarm system (ABA)	Kr.	90.000	62.997
Service Subscription Emergency Lighting	Kr.	20.000	13.999
Service subscription Pool in atrium	Kr.	5.000	3.500
Service subscription brandmateriale	Kr.	9.000	6.300
Building network	Kr.	40.000	27.999
Cable TV/Hybridnet	Kr.	145.000	101.495
Repair of external blinds	Kr.	5.000	3.500
Repair of ventilation	Kr.	80.000	55.998
Elevator repair	Kr.	30.000	20.999
Sprinkler repair	Kr.	15.000	10.500
Repair of basin in atrium	Kr.	5.000	3.500
Repair of ABA systems	Kr.	16.000	11.200
Repair of revolving doors	Kr.	8.500	5.950
Repair/replacement of lighting installations	Kr.	15.000	10.500
Repair plumbing, toilet, shower facilities	Kr.	20.000	13.999
Alarm system repair	Kr.	5.000	3.500

Interior and exterior window cleaning	Kr.	140.000	97.996
Service Subscription Mats	Kr.	18.000	12.599
Renovation	Kr.	220.000	153.993
Provisions for ventilation	Kr.	435.000	304.486
Provisions for lifts	Kr.	150.000	104.995
Service Subscription Guard	Kr.	275.000	192.491
Call-outs	Kr.	100.000	69.997
Building insurance	Kr.	300.000	209.991
Landowners' association	Kr.	500.000	349.984
Fee	Kr.	139.000	97.296
Total excl. VAT	kr.	9.455.511	6.618.563

§ 10.4 The lease's share of the stated expenses is estimated at DKK 6,618,563 p.a. excluding VAT.

§ 10.5 The property costs are distributed among the tenants in the property in proportion to the area of the individual lease in relation to the property's total area above ground level at any given time, which is 16,342.30 m². However, expenses that can only be attributed to one or more of the individual leases in the property are distributed among these tenants in proportion to the gross areas involved. The lease's share is 11,439.10 m2 / 16,342.30 m², but can be changed, cf. § 1. As regards expenses for land tax, cover tax and rat control, the expenses are distributed according to a separately specified distribution figure, as these expenses are assessed in relation to the relevant condominium in which the lease is located. The distribution figure and thus the lease's share is 11,439.10 m2 / 12,679.70 m2 as **far as these costs are concerned.** The landlord is entitled to change the distribution key in the rental meter, condominium or property areas at any time and without notice, as long as it is not to the detriment of the tenant.

§ 10.6 If the Landlord deems that a Tenant's business will result in an increase beyond the usual in the costs of, for example, refuse collection or other expenses, the Landlord may impose a proportionately larger payment of the expenses in question on the Tenant and thus deviate from the otherwise applicable distribution principles.

§ 10.7 To cover the property expenses, the Tenant pays a monthly advance contribution, which is deducted from the final calculated expense for the financial year in question. This contribution on account may be changed at any time and without notice so that it always covers the actual expenses. The landlord must prepare a budget follow-up at least 1 time a year, so that the actual costs correspond to the on-account contributions to the greatest extent possible.

§ 10.8 The final statement of the property expenses shall be made once a year as of 1 January. At the tenant's request, the landlord must document the expenses incurred.

§ 10.9 If, as a result of an error or oversight, the Landlord has omitted to include an expense item in the accounts or included this with an amount that is too small, the Landlord is notwithstanding

The amount of this is entitled either to transfer the omitted item of expenditure or a possible difference to the following consumption accounts or to collect the amount when the error is found.

§ 10.10 The tenant has been made aware that new legislation has been adopted in the area of taxation and determination of public valuation for commercial properties and residential rental properties. The new property valuation and tax system means that the tax base for the property in which the lease is located will be determined in the future on the basis of completely new valuation principles. The new rules for taxation entered into force on 1 January 2022 with adopted transitional arrangements until 2026, when the tax restructuring is expected to be implemented in its entirety.

The tenant has been made aware of and accepts that the implementation of the new tax system means that the tax base and the derived taxes for the property will probably be changed in the future. The detailed tax consequences for the property and thus indirectly for the Tenant are still unknown. In the municipalities that levy cover tax, further increases in property taxes are to be expected. The parties have agreed that the Landlord is not responsible for any increase in the property's property taxes, including land tax and fees. The Landlord is therefore entitled – regardless of the time – to collect property taxes, including land tax and fees from the Tenant for the relevant rental period, if the property tax paid on account, including land tax and tax collected by the Danish Tax Agency has been assessed too low in relation to a new property assessment. The Landlord must submit his/her claim for additional collection against the Tenant no later than in connection with the Landlord's calculation of the eviction claim against the Tenant.

The Tenant is separately made aware that the Landlord has not received the correct or final property tax ticket for 2025 for the condominium of which the lease is a part, which is why the estimates stated in section 10.1 regarding land tax, cover tax and rat control have been made on the basis of the property tax ticket for 2023 for the condominium. The landlord thus makes a separate reservation to carry out post-collection and any adjustment of the amount on account if this proves necessary in relation to the final assessed amounts. The Tenant shall be entitled to appeal the property valuation on behalf of the Landlord and the Landlord shall immediately submit the property valuation to the Tenant when it is received. Costs associated with any complaint are borne by the Renter.

§ 11.

Other expenditure and types of expenditure

§ 11.1 In addition to the rent, cf. section 8, and the expenses mentioned in sections 9, 10 and 12, the Renter must pay the following expenses directly to the supplier:

- Electricity consumption in the rented apartment.
- Disposal of company waste. The placement of waste containers must be done according to the Landlord's instructions.

§ 11.2 If, despite the direct customer relationship between the Renter and the supplier, the Landlord is liable to the supplier for any of the above-mentioned deliveries, the Landlord may demand a separate deposit as security for the Renter's payments.

§ 12

Shared facilities

§ 12.1 In the property, the Tenant, like the other Tenants in the property, has access to common facilities including a canteen, common meeting rooms, etc. The tenant is obliged to participate in the operation of these common facilities and to participate in the tenant committee.

The landlord guarantees that the property has a jointly serviced canteen arrangement and a serviced meeting center and auditorium.

Common costs are paid in addition to the rent in section 8, heating and hot water § 9, expenses for the profit and loss account § 10 and other expenses § 11.

§ 12.2 For the tenants' association accounts 2025, the expenses for the tenants' association are budgeted as follows:

The property's area above ground:		16.342,30	
The lease's share above ground:			11.439,10
Expenses:		**The property's share**	**Share of the lease**
Planting	Kr.	135.000	94.496
Cleaning of common areas incl. can-thaw	Kr.	1.300.000	909.959
Porcelain, etc.	Kr.	75.000	52.498
Heat consumption for the canteen	Kr.	95.000	66.497
Subscriptions to the canteen	Kr.	262.000	183.392
Repair and maintenance of the canteen	Kr.	150.000	104.995
Telephone for the kitchen	Kr.	32.000	22.399
Furniture for the kitchen	Kr.	10.000	7.000

Booking system service	Kr.	55.000	38.498
Provisions TV screens	Kr.	18.000	12.599
Fee	Kr.	29.000	20.299
Total excl. VAT	**kr.**	**2.161.000**	**1.512.633**

§ 12.3 The lease's share of the expenses for the tenant committee is estimated at DKK 1,512,633 p.a. excluding VAT.

§ 12.4 The costs of the common facilities are distributed among the tenants in the property in proportion to the area of the individual lease in relation to the property's total area above ground at any given time, which is 16,342.30 m². However, expenses that can only be attributed to one or more of the individual leases in the property are distributed among these tenants in proportion to the gross areas involved. The lease's share is 11,439.10 m2 / 16,342.30 m², as long as it is not to the detriment of the tenant.

§ 12.5 The final statement of expenses for the tenant committee is made once a year, as of 1 January.

§ 13.

Pristals/Percent Regulation

§ 13.1 The rent (excluding the rent supplement) is adjusted once a year with the percentage change in the net price index. The percentage is calculated to two decimal places. The net price index used has 2015 = 100 and is defined in more detail in Consolidated Act No. 76 of 3 February 1999.

§ 13.2 The adjustment shall take place every year on 1 July accumulating on the basis of the rent in force at the time of adjustment with the percentage change in the net price index. The first adjustment for the total lease will take place on 1 July 2026 on the basis of the percentage change in the net price index from 1 April 2025 to 1 April 2026.

§ 13.3 If the statutory order on the calculation of the net price index or the calculation methods therefor is amended, the adjustment of the rent shall be made in accordance with rules that correspond as closely as possible to the principles applicable in the above-mentioned Act and the principles currently applied.

§ 13.4 Even if the Landlord forgets to make one or more adjustments to the rent in accordance with this provision, the Landlord does not lose the right to make the forgotten adjustments at any later time and thus demand the Tenant the resulting rent increase with retroactive effect, unless the Landlord has expressly waived this.

§ 13.5 If the annual rent is adjusted to the market rent, cf. § 15, or is adjusted as a result of taxes and duties, cf. § 12, and is otherwise adjusted as a result of improvements or other adjustment provisions that may be introduced by changes in the rental legislation, the net price index adjustment shall continue so that the net price index adjustment is calculated on the basis of the new regulated rent.

§ 14.

Adjustment of rent to market rent

§ 14.1 Each party may demand that the rent (excluding the Rent Supplement) be adjusted to the market rent in accordance with the rules in Section 13 of the Commercial Lease Act, however, no earlier than 1 July 2035.

§ 14.2 Market rent does not only mean the rent that can be obtained by letting the lease for the use stipulated in this contract, but also the rent that can be obtained by letting for another use.

§ 14.3 The tenant will never be able to demand a reduction in the rent to an amount lower than the rent at the commencement of the lease with the addition of adjustments in accordance with § 13.

§ 15.

Maintenance and renewals

§ 15.1 Expenses for maintenance of the property's building envelope, which means the roof, facades and the exterior of doors and windows – except shop doors and windows – are covered

Finally, by the landlord, whereas other maintenance, cleaning and renewal expenses are paid by the tenants through the property accounts, cf. section 10.

§ 15.2 Any internal cleaning and maintenance of the lease is thus the responsibility of the Tenant. The tenant's duty of maintenance includes, among other things, renewal of paint, wall cladding, whitening, floor coverings, etc., maintenance and replacement of locks, keys, fittings, windows, taps, sinks and toilet bowls and other sanitary installations, electrical installations, including white goods and fittings of all kinds, cleaning of water traps with drains from sinks, and cleaning and maintenance of all other installations in the rented premises. The aforementioned enumeration of the elements of the Tenant's maintenance obligation is not exhaustive, but only examples.

§ 15.3 Any internal cleaning and maintenance of the Tenancy as a result of deterioration through wear and tear is the responsibility of the Tenant and must be carried out as often as necessary for the sake of the nature of the property and the rented property.

§ 15.4 The Landlord may require the Renter to have the maintenance and repair work carried out immediately when a defect has been detected.

§ 15.5 If the Renter does not fulfil a maintenance or repair work required of him without postponement after being requested in writing by the Landlord, the Landlord may have the work carried out at the Renter's expense.

§ 15.6 The tenant may not demand a reduction in the rent or any form of compensation for the time spent on the above-mentioned maintenance, repair and/or rebuilding work. However, the Landlord is liable for damages according to the general rules of Danish law if the work that is the responsibility of the Landlord in this connection is of such a scope that they exclude the Renter from carrying out his business.

§ 15.7 The landlord is entitled, but not obligated, to carry out an annual review of the rented property and the property in general with a view to assessing the state of maintenance, etc.

§ 15.8 The landlord is entitled to initiate work both inside and outside the leased premises in accordance with the rules in Chapter 5 of the Commercial Lease Act. Changes that significantly and permanently change the identity of the rented property require the Renter's consent.

§ 16.

House rules and use of outdoor and common areas

§ 16.1 It is the Tenant's responsibility to observe that there is good order in and around the rented property, and that this is managed in such a way that the interests of the Landlord and the other tenants are not violated, thereby emphasizing in particular

that the Tenant must handle the rented property and its accessories properly as well as the property in general,

that bicycles may not be parked outside the designated and designated racks. Cars belonging to the Renter and his staff and visitors may only be parked on the property according to the Landlord's instructions.

§ 16.2 The Landlord may at any time draw up house rules and regulations that the Tenant is obliged to strictly observe.

§ 16.3 If the Renter, without the Landlord's approval or in violation of the terms of such agreement, erects signs, flagpoles, awnings or the like on or near the property, cf. hereby § 2 of the Contract, the Landlord is entitled to remove the items in question at the Renter's expense and risk without prior notice. In the same way, the Landlord is entitled to remove effects, such as advertisements, clothes racks, display cabinets, etc., which the Tenant has erected in the property's outdoor and/or common

areas without the Landlord's approval or in violation of the terms of such a law. Such removed items are stored by the Landlord at the Renter's expense and risk.

§ 16.4 The Tenant's failure to comply with the Landlord's instructions and requirements with regard to signage, advertising, clothes racks, display cabinets, etc. is considered a material breach of the tenancy and entitles the Landlord to terminate and terminate it in accordance with the rules of the Commercial Tenancy Act, Chapters 11 and 12.

§ 16.5 The Tenant undertakes to vacate storage rooms that also function as security rooms within the legal time frame in force at any given time.

§ 16.6 Regardless of whether part of the property's common area is included in the gross area of the leased property, the Landlord has the sovereign disposal of all common areas as well as of all outdoor areas, be it pavements, courtyards and all other common areas, e.g. stairs, elevations, etc. This means that the Landlord has the sovereign disposal of these areas, including for the benefit of third parties and both for remuneration and without remuneration. For example, the landlord is allowed to rent out for advertising spaces, mobile antennas, etc.

§ 17.

Responsibility and risk

§ 17.1 The tenant takes care of taking out commercial insurance covering fire, theft and operating loss before the date of entry into force, i.e. before the furnishing of the rented premises with furniture, etc., covering fire, theft and operating losses.

§ 17.2 Should damage occur to the Tenant's property (e.g. furniture, etc.) during the term of the tenancy as a result of errors, defects or omissions in the rented property, the Landlord can only be held liable for this if the Landlord has acted negligently.

§ 17.3 If the Landlord is liable for damages pursuant to the above, the liability per event of damage may not exceed an amount corresponding to the deposit currently paid by the Renter at the time of the damage.

§ 18.

Moving out and returning the rented property

§ 18.1 At the end of the lease, the Tenant must no later than 12 noon on the day the leased property is vacated, even if it is a public holiday or the day before a public holiday, return the rented property with what belongs to it, in the same condition as at the time of handover, which means newly renovated in accordance with § 7, Appendix 4a (The Original Areas) and Appendix 3.2 and Appendix 4b (The New Areas), i.e. freshly painted on all paintable surfaces, with newly treated floor surfaces and all installations cleaned and in full functional condition and otherwise well maintained and cleaned. The departing Tenant is obliged to pay rent for the time it takes to renovate the premises.

§ 18.2 Any of the parties may demand that a joint inspection of the rented property no later than 14 days before the moving date is held in order to agree on the scope and implementation of the Tenant's renovation obligation. If renovation has not been carried out – or in the Landlord's discretion not carried out satisfactorily – before the tenant's handover, the renovation will take place at the Landlord's request and at the Tenant's expense. The Landlord may instead demand that the Tenant's lack of renovation obligations be capitalised and that the amount thus determined is paid in cash by the Tenant at the end of the lease. In that case, the Tenant is not entitled to have the tenancy further renovated. Immediately after this inspection has been carried out, the Landlord and the Tenant each obtain two offers from recognised craftsmen for the execution of the described renovation work and technician fees.

§ 18.3 If the parties cannot reach agreement on the cost of renovation work and technical fees and/or the time spent on the repair, cf. §§ 18.1 and § 18.2, either party may request the appointment of an expert who is appointed by the Danish Institute of Arbitration. The appraiser finally determines the cost of renovation work and technician fees as well as the renovation period that is included in the renovation. The costs of the Danish Institute of Arbitration and the expert are shared between the parties.

§ 18.4 The Tenant's alterations to or special furnishings in the rented premises must be removed and the premises restored, unless the Landlord decides that the special furnishings must remain in the Lease, in which case these must be handed over in the same good condition as the rest of the Lease.

§ 18.5 The Renter is obliged to hand over all keys to locks in doors etc., including such locks that the Renter has placed himself.

§ 18.6 Everything that the Tenant has installed or may later install of furniture in the rented premises, such as counters, cabinets, tables, machines, etc., belongs to the Tenant and must be taken with him at the end of the lease, and a complete restoration must be carried out after removal.

§ 18.7 It has been agreed between the parties that the time limit in section 74(2) of the Commercial Lease Act is set at 3 months.

§ 19.

Tenancy law

§ 19.1 The tenant has a right to pre-lease vacant premises in the property. The tenant has 14 days to return to the landlord's enquiry about a possible pre-tenancy right. Premises must offer on market terms. If the tenant does not return within 14 days, the landlord has the right to rent to another party.

§ 20.

VAT

§ 20.1 All services under this lease are subject to the VAT rate applicable at any given time.

§ 21.

Disputes

§ 21.1 Any dispute that may arise in connection with this lease must be brought before the housing court of first instance.

§ 21.2 However, disputes concerning the Tenant's obligations to repair the Tenant in accordance with clause 20 of the contract shall be settled by an expert appointed by the Danish Institute of Arbitration.

§ 22.

Registration and costs

§ 22.1 If the Tenant has acquired greater rights under this contract than are due to the Tenant under the Commercial Lease Act, he is entitled to have an extract of the lease registered on the property matr.nr on his own initiative. 5ac, Hellerup, however, with respect to current and future burdens, easements and without prejudice for current and future mortgage liens.

§ 22.2 The contract may be cancelled at the request of the Landlord either upon presentation of the Tenant's termination, the Landlord's termination or a printout of the bailiff's book confirming the Tenant's eviction of the tenancy, or the Landlord in some other way proves that the Tenant has vacated the tenancy. The tenant bears any costs in the event of cancellation.

§ 22.3 The parties shall each bear their own costs in connection with the negotiation and preparation of this lease agreement, including fees for their own advisers, lawyer, etc.

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Annex:

1. Drawing dated 28.05.2025
2. Energy label

3. The Danish Business Authority's checklist

3.2 Move-in report – the new areas

4a. Technical description – The original areas 4b. Technical description – The new areas

5. Tenants' association statutes
6. Drawing parking spaces
7. Sign plan
8. Moving out stall

The original copy of the contract remains with the Landlord, with the Renter receiving a copy

Hellerup, the , the

For the landlord: As a tenant:

/s/ Nikolaj Stampe /s/Michael Wolff Jensen

/s/ Thomas Ringstrøm /s/ Lotte Sønderbjerg

Authorised to subscribe for Authorised to subscribe for

Tuborg Havnevej I/S Ascendis Pharma A/S

Exhibit 8.1

Subsidiaries	Jurisdiction of Incorporation
Ascendis Pharma GmbH	Germany
Ascendis Pharma Endocrinology GmbH	Germany
Ascendis Pharma, LLC	USA
Ascendis Pharma Endocrinology, Inc.	USA
Ascendis Pharma, Ophthalmology Division A/S	Denmark
Ascendis Pharma Endocrinology Division A/S	Denmark
Ascendis Pharma Bone Diseases A/S	Denmark
Ascendis Pharma Growth Disorders A/S	Denmark
Ascendis Pharma Oncology Division A/S	Denmark
Ascendis Pharma Europe A/S	Denmark
Ascendis Pharma UK, Limited	United Kingdom
Ascendis Pharma Iberia S.L.	Spain
Ascendis Pharma France SASU	France
Ascendis Pharma Italia S.R.L.	Italy
Ascendis Pharma Sverige AB	Sweden
Ascendis Pharma Switzerland GmbH	Switzerland
Ascendis Pharma Belgium BV	Belgium
ASND Portugal, Unipessoal, Lda.	Portugal

Exhibit 11.1

Insider Trading Compliance Policy

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1 Purpose

Insider Trading is illegal for all individuals regardless of their country of residence. Individuals outside of the US may be prosecuted for violations of Insider Trading rules in the same way individuals in the US may be prosecuted.

"Insider Trading" occurs when any person purchases or sells a security (e.g., Company ordinary shares or American Depositary Shares (ADS) representing ordinary shares) while in possession of "material non-public information" relating to the security. Please see Section 3 below for more information on what constitutes information that is both "material" and "non-public".

Compliance with this Policy is crucial to abide by the laws and regulations, as well as preserve the reputation and integrity of Ascendis Pharma (the "**Company**") and to protect individuals against violating Insider Trading rules and risking criminal charges.

The purpose of this Insider Trading Compliance Policy (the "**Policy**") is to outline your responsibilities to avoid insider trading and implement certain procedures to help you avoid even the appearance of insider trading.

Violation of the Policy by Ascendis Pharma Individuals may cause disciplinary actions, including potentially termination of employment. Further, violations may be reported to relevant law enforcement authorities.

2 Scope & Definitions

In addition to the above, certain definitions used in this Policy:

Ascendis Pharma	Ascendis Pharma A/S and subsidiaries of Ascendis Pharma A/S.
Ascendis Pharma Individuals	All officers, board members, employees and Eligible Consultants of Ascendis Pharma and its subsidiaries.
Eligible Consultants	Consultants who have been i) assigned an@ascendispharma.com e-mail address, ii) granted access to the Ascendis Pharma intranet, or iii) granted an access card allowing unaccompanied access to the premises of Ascendis Pharma, whether appointed directly by Ascendis Pharma or through their employment with consultancy service providers retained by Ascendis Pharma, or iv) identified by Ascendis Pharma's Chief Legal Officer.
Event-Specific Blackout	Please refer to section 5.2 of this Policy.
Excluded Transactions	i) entering into a deposit arrangement with a depositary for purposes of receiving ADSs from the depositary in respect of ordinary shares or warrants or other equity awards exercisable for ordinary shares, ii) exercises of warrants or other equity awards, or the surrender of shares to Ascendis Pharma in payment of the exercise price or in satisfaction of any tax withholding obligations or vesting of equity-based awards that do not involve a market sale of Ascendis Pharma's securities, iii) purchases of Ascendis Pharma's securities from Ascendis Pharma or sales of Ascendis Pharma's securities to Ascendis Pharma, iv) a plan adopted to comply with the Exchange Act Rule 10b5-1 ("**Rule 10b5-1**"), and

	v) Sell-to-cover-tax transactions that are enforced automatically upon vesting of equity awards, when this is governed by the relevant equity plan rules and necessary in order to comply with tax withholding requirements.
Insider	Ascendis Pharma Individuals and anyone else within Ascendis Pharma, or its subsidiaries, who has material, non-public information about Ascendis Pharma and its activities.
Insider Trading	Refers to the purchase or sale of a security by a person who is in possession of "material", "non-public" information relating to the security, see further explanation in section 4.
SEC	The U.S. Securities and Exchange Commission.
Securities	Includes ordinary shares, American Depositary Shares ("**ADSs**") representing ordinary shares, stocks, bonds, notes, debentures, options, warrants, equity and other convertible securities, as well as derivative instruments.
Trading Plan	Transactions under a previously established contract, plan or instruction to trade in Ascendis Pharma's Securities entered into in accordance with Rule 10b5-1.

3 Applicability

This Policy applies to all Ascendis Pharma Individuals.

Ascendis Pharma Individuals are responsible for ensuring that members of their household also comply with this Policy. This includes family members residing with Ascendis Pharma Individuals, anyone else living in the same household as an Ascendis Pharma Individual, and any family members not living with Ascendis Pharma Individuals whose transactions in Ascendis Pharma's Securities are directed by Ascendis Pharma Individuals, or subject to their influence and control. This Policy also applies to any entities controlled by Ascendis Pharma Individuals, including any limited liability companies, corporations, partnerships, or trusts, and transactions by these entities should be treated for the purposes of this Policy and applicable securities laws as if they were for the account of an Ascendis Pharma Individual.

For purposes of clarity, this Policy, including, without limitation, the preclearance policy, blackout periods and prohibited transactions, does not apply to venture capital entities or other institutional investors that may be affiliated with a board member of Ascendis Pharma or for Company equity securities that a board member may be deemed to have beneficial ownership by virtue of such affiliation.

For purposes of clarity, with the exception of the preclearance requirement, this Policy continues to apply to transactions in Ascendis Pharma's Securities even after termination of service to Ascendis Pharma. If you are in possession of material non-public information when your service terminates, you may not trade in Ascendis Pharma's Securities until that information has become public or is no longer material.

4 Explanation of "Insider Trading"

4.1 What is Insider Trading?

"Insider Trading" refers to the purchase or sale of a Security by a person while in possession of "material", "non-public" information relating to that security. Insider trading is illegal and governed by US securities laws.

“Purchase” and “sale” are defined broadly under applicable US securities laws. “Purchase” includes not only the actual purchase of a security, but also any contract to purchase or otherwise acquire a security. “Sale” includes not only the actual sale of a security, but also any contract to sell or otherwise dispose of a security. These definitions extend to a broad range of transactions, including conventional cash-for-share transactions, conversions, the exercise of warrants, transfers, gifts and acquisitions and exercises of options or puts, calls or other derivative securities.

The laws and regulations concerning insider trading are complex, and if Ascendis Pharma Individuals are in doubt they are encouraged to seek guidance from the Chief Legal Officer prior to considering a transaction in Company Securities.

It is generally understood that Insider Trading includes the following:

trading by Insiders while in possession of material, non-public information;
trading by persons other than Insiders while in possession of material, non-public information, if the information either was given in breach of an Insider’s duty to keep it confidential or was misappropriated; and
communicating or tipping material, non-public information to others, including recommending the purchase or sale of a security while in possession of such information.

4.2 What information is “material”?

Information is considered “material” if there is a substantial likelihood that a reasonable investor would consider it important in making a decision to buy, sell or hold a security, or if the information is likely to have a significant effect on the market price of the security.

Material information can be positive or negative and can relate to virtually any aspect of a company’s business or to any type of security, debt or equity.

Also, information that something is likely to happen in the future — or even just that it may happen —could be deemed material.

Examples of material information include (but are not limited to) information about:

the results of clinical trials;
communications sent to, or received from, the European Medicines Agency or the U.S. Food and Drug Administration, or any other marketing authorization government body;
dividends;
corporate earnings or earnings forecasts;
mergers, acquisitions, tender offers or dispositions;
major new products or product developments;
important business developments such as major contract awards or cancellations;
developments regarding strategic collaborators, including VISEN Pharmaceuticals;
the status of regulatory submissions;
management or control changes;
significant borrowing or financing developments including pending public sales or offerings of debt or equity securities;
defaults on borrowings;
bankruptcies;
cybersecurity or data security incidents; and
significant litigation or regulatory actions.

Moreover, material information does not have to be related to a company's business. For example, the contents of a forthcoming newspaper column that is expected to affect the market price of a security can be material.

Questions regarding material information should be directed to Ascendis Pharma's Chief Legal Officer.

In all cases, individuals subject to this Policy bear full responsibility for ensuring their compliance with this Policy, and also for ensuring that members of their household (and individuals not residing in their household but whose transactions are subject to their influence or control) and entities under their influence or control are in compliance with this Policy.

4.3 What is "non-public" information?

Information is "non-public" if it is not available to the general public. In order for information to be considered public, it must be widely disseminated in a manner making it generally available to investors in a Regulation FD (fair disclosure)-compliant method, such as through a press release, a filing with the SEC or a Regulation FD-compliant conference call. The Chief Legal Officer shall have sole discretion to decide whether information is public for purposes of this Policy.

The circulation of rumors, even if accurate and reported in the media, does not constitute effective public dissemination. In addition, even after a public announcement, a reasonable period of time may need to lapse in order for the market to react to the information. Generally, one should allow one (1) full trading day following release of the information to the public as a reasonable waiting period before such information is deemed to be public.

4.4 Who is an Insider?

Insiders include Ascendis Pharma Individuals and anyone else within Ascendis Pharma who has material, non-public information about the Company and its subsidiaries.

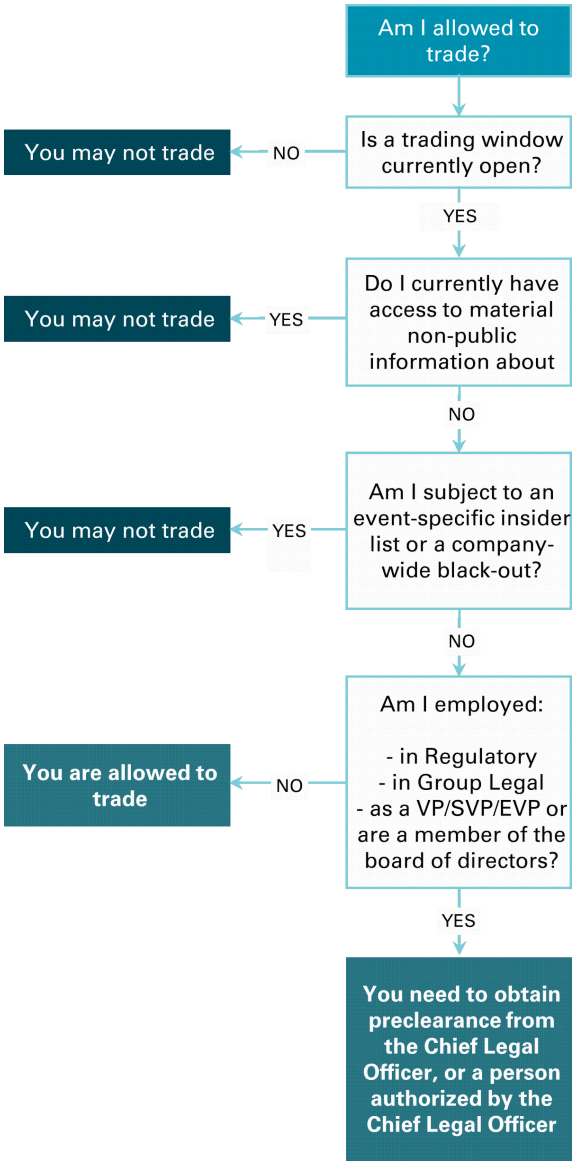
5 Procedures

5.1 Supporting requirements

To minimize the risk of Insider Trading, Ascendis Pharma has put in place below requirements relating to:

Periodic Trading Windows (see 5.1.1)
Event-specific Blackouts (see 5.2)
Specific personal preclearance procedures for senior management and select functions (see 5.2.2)
General handling of material non-public information (see 5.2.3)

The prohibition against Insider Trading and the further instructions contained in sections 5.1.1 - 5.2.2 may be summarized and illustrated in the decision tree shown below (Illustration 1).



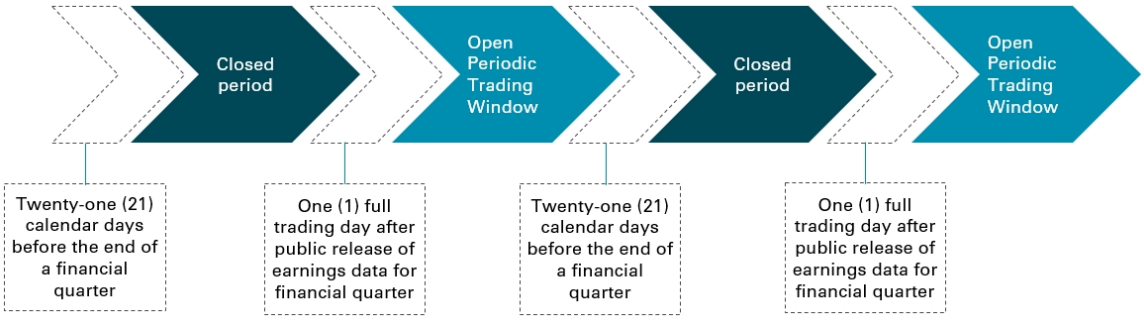
Review of this chart is not a substitute for reading and understanding this Policy.

5.1.1 Periodic Trading Windows

Ascendis Pharma Individuals may only trade during open Periodic Trading Windows. Periodic Trading Windows open on the date falling one (1) full trading day after the public release of earnings data for any financial quarter and close on the date falling twenty-one (21) calendar days prior to the last date of each financial quarter (each, a "**Periodic Trading Window**"). For purposes of the foregoing sentence, a "**trading**

day" is a day on which US national stock exchanges are open for trading. If, for example, Ascendis Pharma were to make an announcement on Monday prior to 9:30 a.m. Eastern Time, then the Periodic Trading Window would open after the close of trading on Tuesday. If an announcement were made on Monday after 9:30 a.m. Eastern Time, then the Periodic Trading Window would open after the close of trading on Wednesday.

The Periodic Trading Windows are illustrated below:



In other words: No Ascendis Pharma Individual nor any family members residing with Ascendis Pharma Individuals, anyone else living in the same household as an Ascendis Pharma Individual, nor any family members not living with Ascendis Pharma Individuals whose transactions in Ascendis Pharma's securities are directed by Ascendis Pharma Individuals, or subject to their influence and control, shall purchase or sell any security of Ascendis Pharma outside of open Periodic Trading Windows. Exceptions to Periodic Trading Windows may be approved only by Ascendis Pharma's Chief Legal Officer or, in the case of exceptions for the Chief Legal Officer, the Chief Financial Officer or, in the case of exceptions for directors, the Board of Directors or Audit Committee of the Board of Directors.

5.2 Prohibition against Insider Trading

No Ascendis Pharma Individual, nor any family members residing with Ascendis Pharma Individuals, anyone else living in the same household as an Ascendis Pharma Individual, nor any family members not living with Ascendis Pharma Individuals whose transactions in Ascendis Pharma's securities are directed by Ascendis Pharma Individuals, shall purchase or sell any type of security while in possession of material, non-public information relating to the security, whether the issuer of such security is Ascendis Pharma or any other company.

5.2.1 Event-Specific Blackouts:

From time to time, whether during a closed period or an open trading window cf. above 5.1.1, the Board of Directors, the Chief Legal Officer or the Chief Financial Officer of Ascendis Pharma determine to suspend trading in Ascendis Pharma's securities by some or all Ascendis Pharma Individuals or others because of developments that have not yet been disclosed to the public. Such suspension is referred to as an "**Event-Specific Blackout**". During an Event-Specific Blackout, all individuals affected should not trade in Ascendis Pharma's securities and should not disclose to others that Ascendis Pharma has implemented an Event-Specific Blackout or otherwise suspended trading.

In case of an Event-Specific Blackout, the Ascendis Pharma Individuals subject to the specific blackout will receive an e-mail notification from the Chief Legal Officer or a person authorized by the Chief Legal Officer. Once Ascendis Pharma Individuals are no longer subject to such Event-Specific Blackout, they will receive an e-mail notification confirming the removal of the trading restrictions.

For the avoidance of doubt, if Ascendis Pharma Individuals do not receive an e-mail notification regarding an Event-Specific Blackout, but are in possession of material non-public information, such Ascendis Pharma Individuals may not trade. Failure by Ascendis Pharma to provide notice does not relieve Ascendis Pharma Individuals of their obligations under this Policy.

5.2.2 Preclearance of all trades by employees in the departments Group Legal and Regulatory, and all senior management (VPs and above management levels) in Ascendis Pharma

All transactions in Ascendis Pharma's Securities by employees in the departments Group Legal and Regulatory, and all senior management (VPs and above management levels) in Ascendis Pharma, other than Excluded Transactions, must be precleared by Ascendis Pharma's Chief Legal Officer or a person authorized by the Chief Legal Officer.

Preclearance should not be understood to represent the legal advice by Ascendis Pharma that the proposed transaction complies with law. Preclearance does not relieve an individual of their responsibility under SEC rules, and none of Ascendis Pharma, the Chief Legal Officer or Chief Financial Officer, or Ascendis Pharma's other employees assume any liability for the legality or consequences of such transaction to the person engaging in such transaction, nor will any of the foregoing have any liability for any delay in reviewing, or refusal of, a request for preclearance submitted pursuant to this Section 5.2.2.

To request a preclearance, Ascendis Pharma Individuals must confirm that they are not aware or in possession of material non-public information either i) by filling out, dating and signing a Preclearance form, which is available on the Ascendis Pharma intranet or through the Computershare portal, and submit it via Ascendis Pharma email to either Ascendis Pharma's Chief Legal Officer or an authorized individual as per directions from the Chief Legal Officer, or ii) by accepting a statement to that effect when using online tools administered by Ascendis Pharma, if applicable.

Preclearance may be granted for a period of up to five (5) trading days but may also be granted for a shorter period of time. The preclearance period will be indicated in the preclearance email. Notwithstanding receipt of preclearance, if the preclearance person becomes aware of material non-public information, becomes subject to an Event-Specific Blackout, or if the Period Trading Window closes before the transaction is effected, the transaction may not be completed. Transactions under a previously established Trading Plan (as defined in Section 7) that have been precleared in accordance with this Policy are not subject to further preclearance.

5.2.3 General handling of Material Non-Public Information

Access to material non-public information about Ascendis Pharma, including Ascendis Pharma's business, earnings or prospects, should be limited to Ascendis Pharma Individuals on a need-to-know basis.

In addition, such information should not be communicated to anyone outside Ascendis Pharma under any circumstances (except in accordance with the Confidentiality Procedure).

Material non-public information must be handled in accordance with our Confidentiality Procedure.

5.2.4 Prohibited Transactions

Ascendis Pharma has determined that there is a heightened legal risk and a heightened appearance of improper or inappropriate conduct if persons subject to this Policy engage in certain types of transactions. Therefore, Ascendis Pharma Individuals shall comply with the following requirements with respect to certain transactions in Ascendis Pharma securities:

5.2.4.1 Short Sales

Short sales of Ascendis Pharma's Securities are prohibited by this Policy. Short sales of Ascendis Pharma's Securities, or sales of shares that the seller does not own at the time of sale, or sales of shares against which the seller does not deliver the shares within twenty (20) days after the sale, evidence an expectation on the part of the seller that the Securities will decline in value, and, therefore, signal to the market that the seller has no confidence in Ascendis Pharma or its short-term prospects.

5.2.4.2 Options

Transactions in puts, calls, or other derivative securities involving Ascendis Pharma's equity securities, on an exchange, on an over-the-counter market, or in any other organized market, are prohibited by this Policy. A transaction in options is, in effect, a bet on the short-term movement of Ascendis Pharma's shares and, therefore, creates the appearance that an Ascendis Pharma Individual is trading based on material non-public information. Transactions in options, whether traded on an exchange, on an over-the-counter market, or any other organized market, may also focus an Ascendis Pharma Individual's attention on short-term performance at the expense of Ascendis Pharma's long-term objectives.

5.2.4.3 Hedging Transactions

Hedging transactions involving Ascendis Pharma's Securities, such as prepaid variable forward sale contracts, equity swaps, collars and exchange funds, or other transactions that hedge or offset, or are designed to hedge or offset, any decrease in the market value of Ascendis Pharma's equity Securities, are prohibited by this Policy. Such transactions allow the Ascendis Pharma Individual to continue to own the covered Securities, but without the full risks and rewards of ownership. When that occurs, the Ascendis Pharma Individual may no longer have the same objectives as Ascendis Pharma's other shareholders.

5.2.4.4 Margin Accounts and Pledging

Ascendis Pharma Individuals are prohibited from pledging Ascendis Pharma Securities as collateral for a loan, purchasing Company Securities on margin (i.e. borrowing money to purchase the securities) or placing Company Securities in a margin account. This prohibition does not apply to cashless exercises of warrants under Ascendis Pharma's equity plans or to situations approved in advance by the Chief Legal Officer or Chief Financial Officer.

5.2.4.5 Partnership Distributions

Nothing in this Policy is intended to limit the ability of an investment fund, venture capital partnership or other similar entity with which a director is affiliated to distribute Company Securities to its partners, members, or other similar persons. It is the responsibility of each affected director and the affiliated entity, in consultation with their own counsel (as appropriate), to determine the timing of any distributions, based on all relevant facts and circumstances, and applicable securities laws.

6 Rule 10b5-1 Trading Plans

The trading restrictions set forth in this Policy, other than those transactions described under "Prohibited Transactions" in Section 5.2.4 of this Policy, do not apply to transactions under a previously established contract, plan or instruction to trade in Ascendis Pharma's Securities entered into in accordance with Rule 10b5-1 (a "**Trading Plan**") that:

has been submitted to and preapproved by Ascendis Pharma's Chief Legal Officer or, in the case of exceptions for the Chief Legal Officer, the Chief Financial Officer, or such other person(s) as the Board of Directors may designate from time to time (each, an "**Authorizing Officer**");

includes a "**Cooling Off Period**" for:

- directors and officers that extends to the later of 90 days after adoption or modification of a Trading Plan or two business days after filing the Form 20-F or Form 6-K disclosing financial results covering the fiscal quarter in which the Trading Plan was adopted, up to a maximum of 120 days; and
- employees and any other persons, other than Ascendis Pharma Individuals, that extends 30 days after adoption or modification of a Trading Plan;

for directors and officers, includes a representation in the Trading Plan that the director or officer is (1) not aware of any material non-public information about Ascendis Pharma or its securities; and (2) adopting the Trading Plan in good faith and not as part of a plan or scheme to evade Rule 10b-5;

has been entered into in good faith at a time when the Ascendis Pharma Individual was not in possession of material non-public information about Ascendis Pharma and not otherwise in a blackout period (*i.e.*, during a Periodic Trading Window and not during an Event-Specific Blackout), and the person who entered into the Trading Plan has acted in good faith with respect to the Trading Plan;

either (1) specifies the amounts, prices, and dates of all security transactions under the Trading Plan, (2) provides a written formula, algorithm, or computer program for determining the amount, price, and date of the transactions, and (3) prohibits the individual from exercising any subsequent influence over the transactions; and

complies with all other applicable requirements of Rule 10b5-1.

The Authorizing Officer may impose other such conditions on the implementation and operation of the Trading Plans as he or she deems necessary or advisable. Individuals may not adopt more than one Trading Plan at a time except under the limited circumstances permitted by Rule 10b5-1 and subject to preapproval by the Authorizing Officer.

Ascendis Pharma Individuals may only modify a Trading Plan outside of a blackout period (i.e., during a Periodic Trading Window and not during an Event-Specific Blackout) and, in any event, when the individual does not possess material non-public information.

Modifications to and terminations of a Trading Plan are subject to preapproval by the Authorizing Officer and modifications of a Trading Plan that change the amount, price, or timing of the purchase or sale of the securities underlying a Trading Plan will trigger a new Cooling-Off Period.

Ascendis Pharma reserves the right to publicly disclose, announce, or respond to inquiries from the media regarding, the adoption, modification, or termination of a Trading Plan and non-Rule 10b5-1 trading arrangements, or the execution of transactions made under a Trading Plan. Ascendis Pharma also reserves the right from time to time to suspend, discontinue, or otherwise prohibit transactions under a Trading Plan if the Authorizing Officer or the Board of Directors, at its discretion, determines that such suspension, discontinuation, or other prohibition is in the best interests of Ascendis Pharma.

Compliance of a Trading Plan with the terms of Rule 10b5-1 and the execution of transactions pursuant to the Trading Plan are the sole responsibility of the person initiating the Trading Plan, and none of Ascendis Pharma, the Authorizing Officer, or Ascendis Pharma's other employees assumes any liability for any delay in reviewing and/or refusing to approve a Trading Plan submitted for approval, nor the legality or consequences relating to a person entering into, informing Ascendis Pharma of, or trading under, a Trading Plan.

7 Interpretation, Amendment, and Implementation of this Policy

The Chief Legal Officer shall have the authority to interpret and update this Policy and all related policies and procedures. In particular, such interpretations and updates of this Policy, as authorized by the Chief Legal Officer, may include amendments to or departures from the terms of this Policy to the extent consistent with the general purpose of this Policy and applicable securities laws.

Actions taken by Ascendis Pharma, the Chief Legal Officer, or any other Company personnel do not constitute legal advice, nor do they insulate you from the consequences of noncompliance with this Policy or with securities laws.

Exhibit 12.1

CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jan Møller Mikkelsen, certify that:

1. I have reviewed this annual report on Form 20-F of Ascendis Pharma A/S (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a 15(f) and 15d 15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: February 11, 2026

By: /s/ Jan Møller Mikkelsen
Name: Jan Møller Mikkelsen
Title: Chief Executive Officer

Exhibit 12.2

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott T. Smith, certify that:

1. I have reviewed this annual report on Form 20-F of Ascendis Pharma A/S (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a 15(f) and 15d 15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: February 11, 2026

By: /s/ Scott T. Smith
Name: Scott T. Smith
Title: Chief Financial Officer and Principal Financial Officer

Exhibit 13.1

CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 20-F of Ascendis Pharma A/S (the "Company") for the year ended December 31, 2025, as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Jan Møller Mikkelsen, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 11, 2026

By: /s/ Jan Møller Mikkelsen
Name: Jan Møller Mikkelsen
Title: Chief Executive Officer

Exhibit 13.2

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 20-F of Ascendis Pharma A/S (the "Company") for the year ended December 31, 2025, as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Scott T. Smith, as Chief Financial Officer and Principal Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 11, 2026

By: /s/ Scott T. Smith
Name: Scott T. Smith
Title: Chief Financial Officer and Principal Financial Officer

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-228576, 333-203040, 333-210810, 333-211512, 333-213412, 333-214843, 333-216883, 333-254101, 333-261550, 333-270088, 333-277519, 333-281916 and 333-285322 on Form S-8 and Registration Statement No. 333-282196 on Form F-3 of our report dated February 11, 2026, relating to the financial statements of Ascendis Pharma A/S and the effectiveness of Ascendis Pharma A/S's internal control over financial reporting appearing in this Annual Report on Form 20-F for the year ended December 31, 2025.

/s/ Deloitte Statsautoriseret Revisionspartnerselskab

Copenhagen, Denmark

February 11, 2026