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

---

# FORM 6-K

---

**REPORT OF FOREIGN PRIVATE ISSUER**
**PURSUANT TO SECTION 13a-16 OR 15d-16**
**UNDER THE SECURITIES EXCHANGE ACT OF 1934**

**For the month of November, 2021**

**Commission File Number: 001-36815**

---

# Ascendis Pharma A/S
**(Exact Name of Registrant as Specified in Its Charter)**

---

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

---

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

## INCORPORATION BY REFERENCE

This report on Form 6-K shall be deemed to be incorporated by reference into the registration statements on Form S-8 (Registration Numbers 333-203040, 333-210810, 333-211512, 333-213412, 333-214843, 333-216883, 333-228576 and 333-254101) and Form F-3 (Registration Numbers 333-209336, 333-211511, 333-216882, 333-223134, 333-225284 and 333-256571) of Ascendis Pharma A/S (the "Company") (including any prospectuses forming a part of such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

---

Furnished as exhibits to this Report on Form 6-K is information regarding the Company's financial results for the fiscal quarter ended September 30, 2021.

**Exhibits**

| Exhibit No. | Description |
|---|---|
| 99.1 | Unaudited Condensed Consolidated Interim Financial Statements. |
| 99.2 | Management's Discussion and Analysis of Financial Condition and Results of Operations. |
| 101.INS | XBRL Instance Document. |
| 101.SCH | XBRL Taxonomy Extension Schema Document. |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document. |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.IAB | XBRL Taxonomy Extension Labels Linkbase Document. |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Ascendis Pharma A/S**

Date: November 10, 2021

By: /s/ Michael Wolff Jensen
Michael Wolff Jensen
Senior Vice President, Chief Legal Officer

Exhibit 99.1

## ASCENDIS PHARMA A/S

## INDEX TO UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

**Unaudited Condensed Consolidated Interim Statements of Profit or Loss and Comprehensive Income / (Loss) for the Three and Nine Months Ended September 30**

| | Notes | Three Months Ended September 30 2021 | Three Months Ended September 30 2020 | Nine Months Ended September 30 2021 | Nine Months Ended September 30 2020 |
|---|---|---|---|---|---|
| | | (EUR'000) | | (EUR'000) | |
| ***Consolidated Interim Statement of Profit or Loss*** | | | | | |
| Revenue | **5** | 1,113 | 2,757 | 2,881 | 6,418 |
| Research and development costs | **4,7** | (58,761) | (64,059) | (230,216) | (185,152) |
| Selling, general and administrative expenses | **7** | (39,284) | (17,523) | (111,876) | (56,243) |
| **Operating profit / (loss)** | | **(96,932)** | **(78,825)** | **(339,211)** | **(234,977)** |
| Share of profit / (loss) of associate | | (3,855) | (3,101) | 19,434 | (6,501) |
| Finance income | | 21,321 | 136 | 44,589 | 1,677 |
| Finance expenses | | (877) | (39,970) | (2,580) | (40,391) |
| **Profit / (loss) before tax** | | **(80,343)** | **(121,760)** | **(277,768)** | **(280,192)** |
| Tax on profit / (loss) for the period | | (5) | 19 | 253 | 202 |
| **Net profit / (loss) for the period** | | **(80,348)** | **(121,741)** | **(277,515)** | **(279,990)** |
| Attributable to owners of the Company | | (80,348) | (121,741) | (277,515) | (279,990) |
| Basic and diluted earnings / (loss) per share | | € (1.47) | € (2.31) | € (5.13) | € (5.64) |
| Number of shares used for calculation (basic and diluted) (1) | | 54,639,597 | 52,715,204 | 54,085,793 | 49,647,471 |
| | | (EUR'000) | | (EUR'000) | |
| ***Consolidated Interim Statement of Comprehensive Income*** | | | | | |
| **Net profit / (loss) for the period** | | **(80,348)** | **(121,741)** | **(277,515)** | **(279,990)** |
| **Other comprehensive income / (loss)** | | | | | |
| *Items that may be reclassified subsequently to profit or loss:* | | | | | |
| Exchange differences on translating foreign operations | | 1,016 | (75) | 2,781 | (136) |
| **Other comprehensive income / (loss) for the period, net of tax** | | **1,016** | **(75)** | **2,781** | **(136)** |
| **Total comprehensive income / (loss) for the period, net of tax** | | **(79,332)** | **(121,816)** | **(274,734)** | **(280,126)** |
| Attributable to owners of the Company | | (79,332) | (121,816) | (274,734) | (280,126) |

(1) A total of 6,046,356 warrants outstanding as of September 30, 2021 can potentially dilute earnings per share in the future but have not been included in the calculation of diluted earnings per share because they are antidilutive for the periods presented. Similarly, a total of 5,527,218 warrants outstanding as of September 30, 2020 are also considered antidilutive for the periods presented and have not been included in the calculation.

## Unaudited Condensed Consolidated Interim Statements of Financial Position

| | Notes | September 30, 2021 | December 31, 2020 |
|---|---|---|---|
| | | (EUR'000) | |
| **Assets** | | | |
| **Non-current assets** | | | |
| Intangible assets | | 5,384 | 5,717 |
| Property, plant and equipment | | 126,295 | 108,112 |
| Investment in associate | **4** | 43,639 | 9,176 |
| Deposits | | 1,713 | 1,375 |
| Marketable securities | **8** | 71,614 | 115,280 |
| | | **248,645** | **239,660** |
| **Current assets** | | | |
| Inventories | **4** | 55,270 | — |
| Trade receivables | | 533 | 387 |
| Other receivables | | 20,258 | 6,957 |
| Prepayments | | 22,239 | 13,994 |
| Marketable securities | **8** | 165,347 | 134,278 |
| Cash and cash equivalents | | 692,941 | 584,517 |
| | | **956,588** | **740,133** |
| **Total assets** | | **1,205,233** | **979,793** |
| **Equity and liabilities** | | | |
| **Equity** | | | |
| Share capital | **9** | 7,638 | 7,217 |
| Distributable equity | | 985,924 | 831,494 |
| | | **993,562** | **838,711** |
| **Non-current liabilities** | | | |
| Lease liabilities | **10** | 95,553 | 85,116 |
| Other payables | | — | 3,162 |
| | | **95,553** | **88,278** |
| **Current liabilities** | | | |
| Lease liabilities | **10** | 6,748 | 6,859 |
| Contract liabilities | | 36 | 363 |
| Trade payables and accrued expenses | | 76,471 | 21,897 |
| Other payables | | 32,362 | 23,384 |
| Income taxes payable | | 501 | 301 |
| | | **116,118** | **52,804** |
| **Total liabilities** | | **211,671** | **141,082** |
| **Total equity and liabilities** | | **1,205,233** | **979,793** |

**Unaudited Condensed Consolidated Interim Statements of Changes in Equity**

| | | Distributable Equity | | | | |
|---|---|---|---|---|---|---|
| | Share Capital | Share Premium | Foreign Currency Translation Reserve | Share-based Payment Reserve | Accumulated Deficit | Total |
| | | | (EUR'000) | | | |
| **Equity at January 1, 2021** | **7,217** | **1,728,747** | **(76)** | **133,101** | **(1,030,278)** | **838,711** |
| Loss for the period | — | — | — | — | (277,515) | **(277,515)** |
| Other comprehensive income / (loss), net of tax | — | — | 2,781 | — | — | **2,781** |
| **Total comprehensive income / (loss)** | **—** | **—** | **2,781** | **—** | **(277,515)** | **(274,734)** |
| **Transactions with Owners** | | | | | | |
| Share-based payment (Note 7) | — | — | — | 52,684 | — | **52,684** |
| Capital increase | 421 | 396,647 | — | — | — | **397,068** |
| Cost of capital increase | — | (20,167) | — | — | — | **(20,167)** |
| **Equity at September 30, 2021** | **7,638** | **2,105,227** | **2,705** | **185,785** | **(1,307,793)** | **993,562** |

| | | Distributable Equity | | | | |
|---|---|---|---|---|---|---|
| | Share Capital | Share Premium | Foreign Currency Translation Reserve | Share-based Payment Reserve | Accumulated Deficit | Total |
| | | | (EUR'000) | | | |
| **Equity at January 1, 2020** | **6,443** | **1,122,097** | **(34)** | **79,931** | **(611,323)** | **597,114** |
| Loss for the period | — | — | — | — | (279,990) | **(279,990)** |
| Other comprehensive income / (loss), net of tax | — | — | (136) | — | — | **(136)** |
| **Total comprehensive income / (loss)** | — | — | **(136)** | — | **(279,990)** | **(280,126)** |
| **Transactions with Owners** | | | | | | |
| Share-based payment (Note 7) | — | — | — | 38,781 | — | **38,781** |
| Capital increase | 729 | 626,460 | — | — | — | **627,189** |
| Cost of capital increase | — | (31,373) | — | — | — | **(31,373)** |
| **Equity at September 30, 2020** | **7,172** | **1,717,184** | **(170)** | **118,712** | **(891,313)** | **951,585** |

**Unaudited Condensed Consolidated Interim Cash Flow Statements for the Nine Months Ended September 30**

| | Notes | Nine Months Ended September 30, 2021 | 2020 |
|---|---|---|---|
| | | (EUR'000) | |
| **Operating activities** | | | |
| **Net profit / (loss) for the period** | | **(277,515)** | **(279,990)** |
| Reversal of finance income | | (44,589) | (1,677) |
| Reversal of finance expenses | | 2,580 | 40,391 |
| Reversal of tax charge | | (253) | (202) |
| Adjustments for non-cash items: | | | |
| Reversal of non-cash consideration relating to revenue | | (1,749) | (2,850) |
| Reversal of share of profit / (loss) of associate | | (19,434) | 6,501 |
| Share-based payment | | 52,684 | 38,781 |
| Depreciation | | 10,784 | 6,462 |
| Amortization | | 333 | — |
| Changes in working capital: | | | |
| Inventories | 4 | (55,270) | — |
| Receivables | | (9,295) | (2,082) |
| Prepayments | | (8,246) | (7,618) |
| Contract liabilities (deferred income) | | (327) | (635) |
| Trade payables, accrued expenses and other payables | | 54,302 | 20,732 |
| **Cash flows generated from / (used in) operations** | | **(295,995)** | **(182,187)** |
| Finance income received | | 2,919 | 1,653 |
| Finance expenses paid | | (1,056) | (1,152) |
| Income taxes received / (paid) | | (207) | 470 |
| **Cash flows from / (used in) operating activities** | | **(294,339)** | **(181,216)** |
| **Investing activities** | | | |
| Investment in associate | | (10,187) | — |
| Acquisition of property, plant and equipment | | (18,907) | (15,596) |
| Reimbursement from acquisition of property, plant and equipment | | — | 4,004 |
| Development expenditures (software) | | (530) | (734) |
| Purchase of marketable securities | | (87,544) | (340,391) |
| Settlement of marketable securities | | 118,512 | 132,650 |
| **Cash flows from / (used in) investing activities** | | **1,344** | **(220,067)** |
| **Financing activities** | | | |
| Payment of principal portion of lease liabilities | | (4,885) | (3,480) |
| Proceeds from exercise of warrants | | 9,209 | 15,274 |
| Net-proceeds from follow-on public offerings | | 367,692 | 580,542 |
| **Cash flows from / (used in) financing activities** | | **372,016** | **592,336** |
| **Increase / (decrease) in cash and cash equivalents** | | **79,021** | **191,053** |
| Cash and cash equivalents at January 1 | | 584,517 | 598,106 |
| Effect of exchange rate changes on balances held in foreign currencies | | 29,403 | (25,705) |
| **Cash and cash equivalents at September 30** | | **692,941** | **763,454** |
| **Cash and cash equivalents include:** | | | |
| Bank deposits | | 692,941 | 719,698 |
| Short-term marketable securities | | — | 43,756 |
| **Cash and cash equivalents at September 30** | | **692,941** | **763,454** |

## Notes to the Unaudited Condensed Consolidated Interim Financial Statements

### Note 1—General Information

Ascendis Pharma A/S, together with its subsidiaries is a biopharmaceutical company applying its innovative TransCon technologies to build a leading, fully integrated biopharmaceutical company. Ascendis Pharma A/S was incorporated in 2006 and is headquartered in Hellerup, Denmark. Unless the context otherwise requires, references to the “Company,” “we,” “us” and “our” refer to Ascendis Pharma A/S and its subsidiaries.

The address of the Company’s registered office is Tuborg Boulevard 12, DK-2900, Hellerup, Denmark.

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 approved these unaudited condensed consolidated interim financial statements on November 10, 2021.

### Note 2—Summary of Significant Accounting Policies

***Basis of Preparation***

The unaudited condensed consolidated interim financial statements of the Company are prepared in accordance with International Accounting Standard 34, “Interim Financial Reporting.” Certain information and disclosures normally included in the annual consolidated financial statements prepared in accordance with International Financial Reporting Standards (“IFRS”) have been condensed or omitted. Accordingly, these unaudited condensed consolidated interim financial statements should be read in conjunction with the Company’s audited annual consolidated financial statements for the year ended December 31, 2020 and accompanying notes, which have been prepared in accordance with IFRS as issued by the International Accounting Standards Board, and as adopted by the European Union.

The accounting policies applied are consistent with those of the previous financial year. A description of our accounting policies is provided in the Accounting Policies section of the audited consolidated financial statements as of and for the year ended December 31, 2020. In addition, the accounting policies for inventories, applied for the first time in this reporting period, are described below.

The preparation of financial statements in conformity with IFRS requires the use of certain significant accounting estimates and requires management to exercise its judgement in the process of applying the Company’s accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the unaudited condensed consolidated interim financial statements are disclosed in Note 3.

***Inventories***

Inventories comprise raw materials, work in progress and finished goods. Work in progress and finished goods comprise service expenses incurred at Contract Manufacturing Organizations, 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. Production processes are complex, where actual yields and consumptions are sensitive to a wide variety of manufacturing conditions. 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. Standard cost variances are reviewed regularly and adjusted to ensure inventories approximate actual costs 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 when incurred. The amount of reversal of write-down of inventories arising from an increase in net realizable value is recognized as a reduction in cost of sales in the period in which the reversal occurs.

Manufacturing of pre-launch inventories are 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 costs. If marketing approval is obtained, prior write-downs of pre-launch inventories are reversed through research and development costs so the inventories are measured at the lower of cost and net realizable value.

When inventories are sold, the cost of inventories is recognized as part of cost of sales in the period in which the related revenue is recognized.

***New and Amended IFRS Standards Adopted by the Company***

Several new amendments and interpretations became applicable for the current reporting period, but do not have an impact on the accounting policies applied by the Company.

## Note 3—Critical Accounting Judgements and Key Sources of Estimation Uncertainty

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

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods. While the application of significant accounting estimates is subject to material estimation uncertainties, management's ongoing revisions of significant accounting estimates have not revealed any material impact on the consolidated interim statements of profit or loss for any of the periods presented.

The unaudited condensed consolidated interim financial statements do not include all disclosures for significant accounting judgements, estimates and assumptions, that are required in the annual consolidated financial statements, and therefore, should be read in conjunction with the Company's audited consolidated financial statements as of and for the year ended December 31, 2020.

Significant judgements made in the process of applying our accounting policies and that have the most significant effect on the amounts recognized in the unaudited condensed consolidated interim financial statements relate to revenue recognition, share-based payment, internally generated intangible assets related to drug development, classification of collaboration agreements and recognition principles related to pre-launch inventories. For the nine months ended September 30, 2021, the Company has for the first time, in connection with determining the grant date fair value of warrants and accordingly, warrant compensation costs, applied the price of the Company's ADSs, each representing one ordinary share of the Company, as input for expected volatility. Details are provided in section "Warrant Compensation Costs". Until December 31, 2020, the expected volatility was calculated using a simple average of daily historical data of comparable publicly traded companies, as the Company did not have sufficient data for the volatility of the Company's own share price.

The key sources of estimation uncertainty that have a significant risk of causing a material adjustment to the carrying amount of assets and liabilities within the next financial year, primarily relate to recognition and measurement of accruals and prepayments for manufacturing and clinical trial activities.

Other than as set out below, there have been no other changes to the application of significant accounting judgements, or estimation uncertainties regarding accounting estimates compared to December 31, 2020.

### 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 over the vesting period as research and development costs or selling, general and administrative expenses, as appropriate, 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 values of the warrants granted. Estimating fair values requires the Company to apply generally accepted valuation models and apply these models consistently according to the terms and conditions of the specific warrant program. Under all warrant programs, the Black-Scholes option-pricing model has been applied to determine the fair value of warrants granted. Subjective judgements and assumptions, which are subject to estimation uncertainties, need to be exercised in determining the appropriate input to the valuation model. 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. For the nine months ended September 30, 2021, the expected volatility has been calculated using the price of the Company's ADSs, each representing one ordinary share of the Company.

## Note 4—Significant Events in the Reporting Period

### *Impact from COVID-19 Pandemic*

The COVID-19 pandemic has affected countries where we are operating, where we have planned or have ongoing clinical trials, and where we rely on third-parties to manufacture preclinical, clinical and commercial supply.

We monitor the risks from this pandemic closely, and work with relevant stakeholders to avoid and limit disruptions, and to develop and establish working measures. However, while COVID-19 continues to impact global societies, the uncertainty related to the duration and direction of the pandemic makes the future impact from COVID-19, including the magnitude of any impact on our operational results, highly uncertain and unpredictable. At the reporting date, COVID-19 did not have a direct material impact on the consolidated interim financial statements.

### *VISEN Pharmaceuticals Investment*

On January 8, 2021, the Company entered into an equity investment of $12.5 million in its associate, VISEN Pharmaceuticals (“VISEN”), as part of VISEN’s $150 million Series B financing. Following VISEN’s Series B financing, the Company retained approximately 44% of VISEN’s issued and outstanding shares. As a result, the Company recognized a non-cash gain in the first quarter of 2021 of €42.3 million, which is presented as part of “Share of profit / (loss) of associate” in the consolidated interim statement of profit or loss. The Series B financing did not change the Company’s accounting treatment of VISEN.

### *U.S. Regulatory Approval of SKYTROFA® (lonapegsomatropin-tcgd)*

On August 25, 2021, the U.S. Food and Drug Administration (the “FDA”), approved TransCon hGH, known by its brand name SKYTROFA and its INN 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. As a once-weekly injection, SKYTROFA (lonapegsomatropin-tcgd) is the first FDA approved product that delivers somatropin (growth hormone) by sustained release over one week.

As a result of obtaining marketing approval for SKYTROFA (lonapegsomatropin-tcgd), the Company reversed prior write-down of prelaunch inventories through research and development costs. The reversal had a positive impact of €53.2 million on the Company’s statement of profit or loss. At the reporting date, inventories comprise raw materials and work in progress.

No revenue was recognized for SKYTROFA (lonapegsomatropin-tcgd) for the nine months period ended September 30, 2021.

### *Completion of Follow-on-public Offering*

On September 1, 2021, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Evercore Group L.L.C. and SVB Leerink LLC, as representatives (the “Representatives”) of the several underwriters named therein (collectively, the “Underwriters”), pursuant to which the Company agreed to issue and sell 2,500,000 ADSs, each of which represents one ordinary share of the Company, DKK 1 nominal value per share, to the Underwriters (the “Offering”). The ADSs were sold at a public offering price of $160.00 per ADS, and were purchased by the Underwriters from the Company at a price of $152.00 per ADS. Under the terms of the Underwriting Agreement, the Company granted the Underwriters the right, for 30 days, to purchase from the Company up to 375,000 additional ADSs at the public offering price, less the underwriting commissions. On September 2, 2021, the Underwriters exercised their option to purchase the additional 375,000 ADSs in full.

On September 7, 2021, the Offering closed and the Company completed the sale and issuance of an aggregate of 2,875,000 ADSs. The Company received net proceeds from the Offering of $436.5 million, or €367.7 million, after deducting the Underwriters’ commissions and offering expenses payable by the Company.

**Note 5—Revenue**

The Company's revenue is primarily generated from three license agreements, which were entered into in 2018. The licenses grant VISEN exclusive rights to develop and commercialize TransCon hGH, TransCon PTH and TransCon CNP in Greater China. As consideration for the granting of such rights, the Company received up-front, non-refundable, non-cash consideration of $40.0 million in the form of 50% ownership in VISEN. At the reporting date, the Company retains approximately 44% of VISEN's issued and outstanding shares.

Consideration received is recognized partly as license revenue, and partly as rendering of services over time. In addition to granting exclusive rights, the Company provides clinical trial supply and development services to VISEN.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | (EUR'000) | | (EUR'000) | |
| **Revenue from external customers** | | | | |
| Revenue from rendering of services (recognized over time) | 203 | 164 | 599 | 2,255 |
| Sale of clinical supply (recognized at a point in time) | 316 | 1,959 | 533 | 2,206 |
| "Right-to-use" licenses (recognized at a point in time) | 594 | 634 | 1,749 | 1,957 |
| **Total revenue (1)** | **1,113** | **2,757** | **2,881** | **6,418** |
| **Attributable to** | | | | |
| VISEN Pharmaceuticals | 1,004 | 2,757 | 2,554 | 6,418 |
| Other collaboration partners | 109 | — | 327 | — |
| **Total revenue** | **1,113** | **2,757** | **2,881** | **6,418** |
| **Revenue by geographical location** | | | | |
| North America | 702 | 634 | 2,076 | 1,957 |
| China | 411 | 2,123 | 805 | 4,461 |
| **Total revenue** | **1,113** | **2,757** | **2,881** | **6,418** |

(1) For the three months ended September 30, 2021 and 2020, and for the nine months ended September 30, 2021 and 2020, "Total revenue" includes recognition of previously deferred revenue/internal profit from associate of €0.6 million and €0.6 million, and of €1.7 million and €2.8 million, respectively.

**Note 6—Segment Information**

The Company is managed and operated as one business unit. No separate business areas or separate business units have been identified in relation to product candidates or geographical markets. Accordingly, no additional information on business segments or geographical areas is disclosed.

## Note 7—Warrants and Share-based Payment

### *Share-based Payment*

Ascendis Pharma A/S has established warrant programs and equity-settled share-based payment transactions, as an incentive for all its employees, members of its Board of Directors and select consultants.

Warrants are granted by the Company's Board of Directors in accordance with authorizations given to it by the shareholders of the Company. As of September 30, 2021, 11,174,143 warrants have been granted, of which 19,580 warrants have been cancelled, 4,428,982 warrants have been exercised, 2,168 warrants have expired without being exercised, and 677,057 warrants have been forfeited. As of September 30, 2021, the Company's Board of Directors was authorized to grant up to 2,453,144 additional warrants to employees, board members and select consultants without preemptive subscription rights for the shareholders of the Company. Each warrant carries the right to subscribe for one ordinary share of a nominal value of DKK 1. The exercise price is fixed at the fair market value of the Company's ordinary shares on the date of grant as determined by the Company's Board of Directors. The exercise prices of outstanding warrants under the Company's warrant programs range from €6.48 to €145.5 depending on the grant dates. Vested warrants may be exercised in two or four annual exercise periods. Apart from exercise prices and exercise periods, the programs are similar.

### *Warrant Activity*

The following table specifies the warrant activity during the nine months ended September 30, 2021:

| | Total Warrants | Weighted Average Exercise Price EUR |
|---|---|---|
| **Outstanding at January 1, 2021** | **6,148,004** | **69.97** |
| Granted during the period | 309,425 | 115.21 |
| Exercised during the period | (252,337) | 38.22 |
| Forfeited during the period | (158,736) | 120.76 |
| **Outstanding at September 30, 2021** | **6,046,356** | **71.91** |
| **Vested at September 30, 2021** | **3,777,047** | **49.61** |

### *Warrant Compensation Costs*

Warrant compensation costs are determined with a basis in the grant date fair value of the warrants granted and recognized over the vesting period as research and development costs or as selling, general and administrative expenses. For the three months ended September 30, 2021 and 2020, and for the nine months ended September 30, 2021 and 2020, warrant compensation costs recognized in the consolidated interim statement of profit or loss was €13.3 million and €10.4 million, and €52.7 million and €38.8 million, respectively.

**Note 8—Marketable Securities**

Marketable securities are measured at amortized cost, and fair values are determined based on quoted market prices (Level 1 in the fair value hierarchy).

The composition of the portfolio is specified in the following table:

| | September 30, 2021 | | December 31, 2020 | |
|---|---|---|---|---|
| | Carrying amount | Fair value | Carrying amount | Fair value |
| | (EUR'000) | | | |
| **Marketable securities** | | | | |
| U.S. Treasury bills | — | — | 46,243 | 46,245 |
| U.S. Government bonds | 80,044 | 80,056 | 62,088 | 62,101 |
| Commercial papers | 2,158 | 2,158 | 10,583 | 10,581 |
| Corporate bonds | 136,204 | 136,128 | 121,282 | 121,234 |
| Agency bonds | 18,555 | 18,556 | 9,362 | 9,369 |
| **Total marketable securities** | **236,961** | **236,898** | **249,558** | **249,530** |
| **Classified based on maturity profiles** | | | | |
| Non-current assets | 71,614 | 71,580 | 115,280 | 115,277 |
| Current assets | 165,347 | 165,318 | 134,278 | 134,253 |
| **Total marketable securities** | **236,961** | **236,898** | **249,558** | **249,530** |
| **Specified by rate structure** | | | | |
| Fixed rate | 220,163 | 220,100 | 175,757 | 175,732 |
| Floating rate | 14,640 | 14,640 | 16,975 | 16,972 |
| Zero-coupon | 2,158 | 2,158 | 56,826 | 56,826 |
| **Total marketable securities** | **236,961** | **236,898** | **249,558** | **249,530** |
| **Specified by investment grade credit rating** | | | | |
| Prime | 6,529 | 6,529 | 7,716 | 7,714 |
| High grade | 116,055 | 116,057 | 142,339 | 142,352 |
| Upper medium grade | 112,270 | 112,206 | 99,503 | 99,464 |
| Lower medium grade | 2,107 | 2,106 | — | — |
| **Total marketable securities** | **236,961** | **236,898** | **249,558** | **249,530** |

The Company's marketable securities are all denominated in U.S. Dollars. At September 30, 2021 and December 31, 2020, the portfolio has a weighted average duration of 6.1 and 6.0 months for current positions, and 17.6 and 17.3 months for non-current positions, respectively. At September 30, 2021 and December 31, 2020, the entire portfolio has a weighted average duration of 9.6 months and 11.2 months.

All marketable securities have investment grade ratings, and accordingly, the risk from probability of default is low. The risk of expected credit loss over marketable securities has been considered, including the hypothetical impact arising from the probability of default which is considered in conjunction with the expected loss given default from securities with similar credit ratings and attributes. This assessment did not reveal a material expected credit loss, and accordingly, no provision for expected credit loss has been recognized.

### Note 9—Share Capital

The share capital of Ascendis Pharma A/S consists of 56,877,723 outstanding shares at a nominal value of DKK 1, all in the same share class.

### Note 10 —Lease Liabilities

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

Maturity analysis for lease liabilities recognized in the consolidated statements of financial position at September 30, 2021 is specified below.

| | < 1 year | 1-5 years | >5 years | Total contractual cash-flows | Carrying amount |
|---|---|---|---|---|---|
| | | | (EUR’000) | | |
| **September 30, 2021** | | | | | |
| Lease liabilities | 6,840 | 47,653 | 70,054 | 124,547 | 102,301 |
| **Total lease liabilities** | **6,840** | **47,653** | **70,054** | **124,547** | **102,301** |

### Note 11—Subsequent Events

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

**ASCENDIS PHARMA A/S**

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

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated interim financial statements, including the notes thereto, included with this report and the section contained in our Annual Report on Form 20-F for the year ended December 31, 2020 – "Item 5. Operating and Financial Review and Prospects". The following discussion is based on our financial information prepared in accordance with International Accounting Standard 34, "Interim Financial Reporting." Certain information and disclosures normally included in the consolidated financial statements prepared in accordance with International Financial Reporting Standards ("IFRS") have been condensed or omitted. IFRS as issued by the International Accounting Standards Board, and as adopted by the European Union, might differ in material respects from generally accepted accounting principles in other jurisdictions.*

## Special Note Regarding Forward-Looking Statements

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

- the timing or likelihood of regulatory filings and approvals for our product candidates, including our expectations regarding approval of our Marketing Authorization Application ("MAA") for TransCon Growth Hormone ("TransCon hGH");
- our expectations regarding the commercial availability of TransCon hGH, known by its brand name SKYTROFA (lonapegsomatropin-tcgd), in the United States and related patient support services;
- the commercialization of TransCon hGH and our other product candidates, if approved;
- our commercialization, marketing and manufacturing capabilities of TransCon hGH and our other product candidates and associated devices;
- the scope, progress, results and costs of developing our product candidates or any other future product candidates, and conducting preclinical studies and clinical trials;
- our pursuit of oncology as our second of three independent therapeutic areas of focus, and our development of a pipeline of product candidates related to oncology;
- our expectations regarding the potential market size and the size of the patient populations for TransCon hGH and our other product candidates, if approved for commercial use;
- our expectations regarding the potential advantages of TransCon hGH and our other product candidates over existing therapies;
- our ability to enter into new collaborations;
- our expectations with regard to the ability to develop additional product candidates using our TransCon technologies and file Investigational New Drug Applications ("INDs") or similar for such product candidates;
- our expectations with regard to the ability to seek expedited regulatory approval pathways for our product candidates, including the potential ability to rely on the parent drug's clinical and safety data with regard to our product candidates;
- our expectations with regard to our current and future collaboration partners to pursue the development of our product candidates and file INDs or similar for such product candidates;
- our development plans with respect to TransCon hGH and our other product candidates;
- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;
- the implementation of our business model and strategic plans for our business, TransCon hGH and our other product candidates and technologies, including global commercialization strategies;
- the scope of protection we are able to establish and maintain for intellectual property rights covering TransCon hGH and our other product candidates;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our financial performance;
- developments and projections relating to our market conditions, competitors and industry; and
- the potential effects on our business of the worldwide COVID-19 pandemic.

These forward-looking statements are based on senior management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this 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 in our Annual Report on Form 20-F for the year ended December 31, 2020 — "Item 3.D. Risk Factors". 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 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 report and the documents that we reference in this report and have filed as exhibits to this 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 Securities and Exchange Commission after the date of this report. We qualify all of our forward-looking statements by these cautionary statements.

## Overview

We are applying our innovative TransCon technologies to build a leading, fully integrated biopharmaceutical company and develop a pipeline of product candidates with potential best-in-class profiles to address unmet medical needs. We currently have a pipeline of multiple independent endocrinology rare disease and oncology product 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 U.S. Food and Drug Administration (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. We also have submitted a regulatory application for marketing approval for TransCon hGH for the treatment of pediatric growth hormone deficiency ("GHD") during 2020 to the European Medicines Agency (the "EMA"). We are building our global commercial presence, starting with a focus in the United States where our initial U.S. commercial organization is in place to support the U.S. launch of SKYTROFA (lonapegsomatropin-tcgd).

In 2018, we co-founded VISEN Pharmaceuticals ("VISEN"), a company established to develop and commercialize our endocrinology rare disease therapies in the People's Republic of China, Hong Kong, Macau and Taiwan ("Greater China"). In connection with the formation of VISEN, we received 50% ownership in the outstanding shares of VISEN and concurrently with the rights we granted to VISEN for TransCon hGH, TransCon PTH and TransCon CNP, entities affiliated with Vivo Capital and Sofinnova Ventures purchased shares in VISEN for an aggregate purchase price of $40 million in cash. On January 8, 2021, we completed an equity investment of $12.5 million in VISEN as part of VISEN's $150 million Series B financing. Following VISEN's Series B financing, we retained approximately 44% of VISEN's issued and outstanding shares.

We had a net loss of €277.5 million for the nine months ended September 30, 2021, and a net loss of €419.0 million for the year ended December 31, 2020. Our total equity was €993.6 million as of September 30, 2021 compared to €838.7 million as of December 31, 2020.

## TransCon Technologies

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

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

## TransCon hGH

TransCon hGH is an investigational once-weekly prodrug designed to deliver somatropin over a one-week period. The released somatropin has the same 191 amino acid sequence as daily somatropin. TransCon hGH is approved by the FDA in the U.S. under the brand name SKYTROFA (lonapegsomatropin-tcgd) 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. TransCon hGH is under review by the EMA as a once-weekly treatment for pediatric GHD. Based on discussions with the EMA, we believe our submission is on track to obtain a positive opinion on TransCon hGH for the treatment of pediatric GHD from the EMA's Committee for Medicinal Products for Human Use ("CHMP") in the fourth quarter of 2021. European Commission approval for TransCon hGH is expected up to 67 days after the anticipated positive CHMP opinion, which the Company expects to occur late 2021 or in early 2022.

SKYTROFA single-use, prefilled cartridges are available in the U.S. in nine dosage strengths, allowing for convenient dosing flexibility. They are designed for use only with the SKYTROFA® Auto-Injector and may be stored at room temperature for up to six months. The recommended dose of SKYTROFA (lonapegsomatropin-tcgd) for treatment-naïve patients and patients switching from daily somatropin is 0.24 mg/kg body weight, administered once weekly. Somatropin released from SKYTROFA (lonapegsomatropin-tcgd) produces a dose linear insulin-like growth factor-1 response and the dosage of SKYTROFA (lonapegsomatropin-tcgd) may be individualized and titrated based on response.

In the body, a similar distribution pattern to that from daily somatropin is expected once somatropin is released from TransCon hGH. We used daily growth hormone as an active comparator in our clinical studies, allowing us to directly compare the activity of TransCon hGH to daily growth hormone in an identical clinical setting.

Our Phase 3 pediatric program for TransCon hGH consists of the heiGHt, fliGHt and enliGHten Trials. The heiGHt Trial was a randomized, open label, active-controlled Phase 3 registrational trial that enrolled 161 children with GHD who had not previously been treated. The fliGHt Trial was designed to evaluate TransCon hGH in subjects who were primarily treatment experienced with daily somatropin, although a subgroup of younger subjects were treatment-naïve. Nearly all subjects who completed the heiGHt or fliGHt Trials have enrolled in the open-label extension study (the "enliGHten Trial"), which is designed to provide long-term safety data to support the regulatory submissions for TransCon hGH. We initiated the enliGHten Trial in 2017 as the first subjects began to roll over from the heiGHt Trial, and we have enrolled approximately 300 pediatric subjects. Data from enliGHten formed the long-term safety database supporting our Biologics License Application submission to the FDA for TransCon hGH for the treatment of pediatric GHD which was approved in August 2021, as well as submission of a MAA to the EMA, which occurred in September 2020.

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

In September 2020, we filed a Clinical Trial Notification ("CTN") with the Pharmaceuticals and Medical Devices Agency in Japan, to initiate our Phase 3 riGHt Trial of TransCon hGH for the treatment for pediatric GHD. The primary objective of the riGHt Trial is to evaluate and compare the annualized height velocity of 40 Japanese prepubertal treatment-naïve children with GHD treated with weekly TransCon hGH to that of a commercially available daily somatropin formulation at 52 weeks.

In July 2020, the EMA adopted a decision agreeing with the positive opinion from the Paediatric Development Committee ("PDCO"), which approved the proposed Paediatric Investigation Plan for TransCon hGH. The PDCO endorsed the TransCon hGH program as acceptable for assessment of safety and efficacy for the use of TransCon hGH as a treatment for GHD in children from six months to less than 18 years of age, mirroring the population covered by the studies conducted in the program.

In April 2020, we received orphan drug designation from the FDA for TransCon hGH in the United States for the treatment of GHD. The FDA grants orphan designation to drugs that are intended for the treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States, and potentially may be safer or more effective than already approved products.

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

Additionally, we have initiated the foresiGHt Trial, a global Phase 3 study with the aim to demonstrate the metabolic benefits of TransCon hGH in adults with GHD and, in Greater China, VISEN completed the patient enrollment of 154 treatment-naïve, prepubertal children in the ongoing Phase 3 pivotal trial of TransCon hGH in patients with pediatric GHD in March 2021. We intend to pursue other indications for TransCon hGH consistent with our strategy to create sustainable growth.

**TransCon PTH**

We are using our TransCon technology platform to develop TransCon PTH, an investigational once-daily long-acting prodrug of parathyroid hormone ("PTH") as a potential treatment for adult hypoparathyroidism ("HP"), a rare endocrine disorder of calcium and phosphate metabolism. TransCon PTH is designed to replace PTH at physiologic levels for 24 hours each day to address both the short-term symptoms and long-term complications of HP.

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

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

TransCon PTH is currently in Phase 3 development as a treatment for adult HP. In September 2020, we submitted an amendment to our IND to initiate the PaTHway Trial, our North American and European Phase 3 double-blinded, placebo controlled clinical trial evaluating the safety, tolerability and efficacy of TransCon PTH in adults with HP following discussions with the FDA and European regulatory authorities. On July 6, 2021, we announced that the PaTHway Trial reached the target enrollment.

On September 22, 2021, we announced 58-week bone mineral density data ("BMD") from central lab reading in the PaTH Forward Trial, a global Phase 2 trial evaluating the safety, tolerability, and efficacy of TransCon PTH in adult subjects with HP. BMD was measured with non-invasive dual energy x-ray absorptiometry ("DXA").

In PaTH Forward, mean BMD Z-scores, trended towards stabilization and continued normalization at 58 weeks.

**Mean Bone Mineral Density Z-scores by DXA***

| Anatomic region | n | Baseline | Week 26 | Week 58 |
|---|---|---|---|---|
| Lumbar spine (L1-L4) | 42 | 1.6 | 1.0 | 0.9 |
| **Femoral neck** | 43 | 1.0 | 0.5 | 0.5 |
| Total hip | 43 | 1.0 | 0.6 | 0.5 |
| **Forearm/ 1/3 radius** | 41 | 0.3 | 0.3 | 0.3 |

* From central lab reading

On July 6, 2021, we announced the receipt of orphan drug designation for TransCon PTH from the Japanese Ministry of Health, Labor, and Welfare. Furthermore, we announced the acceptance of the CTN for the PaTHway Japan Trial, a single-arm, Phase 3 trial of TransCon PTH in a minimum of 12 Japanese subjects with HP.

On June 2, 2021, VISEN announced IND approval from the Center for Drug Evaluation on the National Medical Products Administration for the Phase 3 clinical trial of TransCon PTH in adult subjects with HP, the PaTHway China Trial.

On May 10, 2021, we announced preliminary 58-week results from the continuing open-label extension ("OLE") portion of the PaTH Forward Trial.

Key Findings of the Preliminary OLE Results of PaTH Forward Trial at 58 weeks

- 58 subjects continued in the open-label extension beyond 58 weeks
- Continued treatment with TransCon PTH demonstrated that:
  - 91% of subjects were off standard of care therapy defined as no active vitamin D and less than or equal to 600 mg/day of calcium supplements
  - Urinary calcium maintained in the normal range
  - Bone markers trended towards the mid-normal levels
  - Quality of life benefits measured by SF-36 continued within normal range
- TransCon PTH was well-tolerated at all doses administered
  - No treatment-related serious or severe adverse events occurred, and no treatment-emergent adverse events (“TEAEs”) led to discontinuation of study drug
  - No change to the safety profile in the OLE portion of the study

As of November 7, 2021, 58 subjects continue in the OLE portion of the PaTH Forward Trial.

In October 2020, the EC granted orphan designation to TransCon PTH for the treatment of HP.

In August 2020, we reported data from the four-week fixed dose, blinded portion of PaTH Forward Trial on SF-36® Health Survey which demonstrated that TransCon PTH significantly improved quality of life and restored physical and mental functioning toward a normal level compared to placebo.

In April 2020, we reported positive top-line results from the four-week fixed dose, blinded portion of our Phase 2 PaTH Forward Trial, which evaluated the safety, tolerability and efficacy of three fixed doses of TransCon PTH using a ready-to-use prefilled pen injector planned for commercial presentation. The goal of PaTH Forward was to identify a starting dose for a pivotal Phase 3 trial, establish a titration regimen for complete withdrawal of SoC, and evaluate TransCon PTH control of serum and urinary calcium. A total of 59 subjects were randomized in a blinded manner to receive fixed doses of TransCon PTH at 15, 18 or 21 µg/day or placebo for four weeks. All doses of TransCon PTH were well-tolerated, and no serious or severe adverse events were shown during this period. No TEAEs led to discontinuation of study drug, and the overall incidence of TEAEs was comparable between TransCon PTH and placebo. Additionally, there were no drop-outs during the four-week fixed dose period.

In June 2018, the FDA granted orphan drug designation for TransCon PTH for the treatment of HP.

**TransCon CNP**

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

In July 2019, we initiated the Phase 2 ACcomplisH Trial to evaluate safety and efficacy of TransCon CNP in children (ages 2-10 years) with achondroplasia. In collaboration with VISEN, we are sponsoring the ACcomplisH China Trial, a randomized, double-blind, placebo-controlled, Phase 2 dose expansion trial to evaluate the safety and efficacy of TransCon CNP in subjects with achondroplasia. The primary endpoint is to evaluate the safety of treatment and its effect on 12-month annualized height velocity. In January 2021, China’s Center for Drug Evaluation of National Medical Products Administration approved VISEN’s IND to conduct the ACcomplisH China Trial.

In July 2020, the EC granted orphan designation for TransCon CNP for the treatment of achondroplasia.

In February 2019, the FDA granted orphan drug designation for TransCon CNP for the treatment of achondroplasia.

In November 2018, we reported preliminary results from a Phase 1 trial in healthy adult subjects, which we believe supported our target product profile for TransCon CNP.

### TransCon Product Candidates within Oncology

In January 2019, we established oncology as our second independent therapeutic area of focus for our TransCon technologies. Our goal is to improve treatment efficacy while limiting or reducing toxicity by applying TransCon technologies to clinically validated drugs, using our unique algorithm for product innovation.

We are conducting preclinical studies within the field of oncology to explore multiple potential product candidates and evaluate systemic as well as localized delivery systems using our TransCon technologies.

We are currently advancing two product candidates:

- TransCon TLR7/8 Agonist is designed for sustained release of TLR7/8 agonist, resiquimod, and intended for intratumoral administration. This product candidate is designed to provide potent activation of the innate immune system in the tumor and draining lymph nodes and to have low risk of systemic toxicity. In December 2020, we filed an IND with the FDA to initiate the clinical program of TransCon TLR7/8 Agonist with the transcendIT-101 Trial and we have initiated the combination therapy arm in transcendIT-101 with TLR7/8 Agonist and a check point inhibitor.
- TransCon IL-2 ß/g is designed for prolonged exposure of an IL-2 variant that selectively activates the IL-2Rß/g, with minimal binding to IL-2Ra. This product candidate is designed to provide potent anti-tumor activity and to have reduced risk of toxicity, such as vascular leak syndrome. In September 2021, we filed an IND with the FDA to initiate the clinical program of TransCon IL-2Rß/g with the IL ßeliege (I'll Believe) Trial.

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

**TransCon Product Candidate Pipeline**


[1]FDA approved on August 25, 2021.
[2]In development in Greater China through strategic investment in VISEN Pharmaceuticals.
[3]Japanese riGHt Trial.
[4]Global foresiGHt Trial.
[5]North American and European PaTHway Trial, Japanese PaTHway Japan Trial.
[6]North America, Europe, and Oceania ACcomplisH Trial.
[7]TranscendIT-101.
[8]IL-ßeliege.

**Results of Operations**

**Impact from COVID-19 Pandemic**

The COVID-19 pandemic has affected countries where we are operating, where we have planned or have ongoing clinical trials, and where we rely on third-parties to manufacture preclinical, clinical and commercial supply.

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

- Encouraging employees to work remotely, reduce travel activity and minimize face-to-face meetings;
- Establishing home offices, and ensuring proper and secure IT infrastructure to improve the safety and efficiency of the remote work environment;
- Implementing remote visits for patients enrolled in our clinical trials, including ensuring safe delivery of clinical drugs; and
- Addressing COVID-19 in relation to logistics and manufacturing at Joint Steering Committees with manufacturing partners.

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

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

While COVID-19 has not had a significant impact on our business, COVID-19 presents elevated risks in certain areas, including:

- In conducting our clinical trials, there is a risk that suppliers experience delays in providing necessary equipment, consumables and services, which could cause temporary delays in clinical trial activities. In addition, there is a risk that patients will elect not to enroll in trials to limit their exposure to medical institutions, which could have a negative impact on clinical trial enrollment and timelines;
- Global demand for COVID-19 vaccines and treatments could result in contract manufacturers not having sufficient capacity to meet scheduled manufacturing. In addition, sourcing of certain types of raw materials, consumables and equipment could result in scheduled manufacturing being delayed or postponed. We are monitoring the global supply chain and as of the date of this report, we have not experienced material delays due to potential effected supply; and
- Our commercial launch strategy could be negatively impacted by (i) patients not being able to see their physicians, and (ii) our commercial team not being able to meet with physicians.

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

For additional description of COVID-19 related risks, please refer to “Item 3D. Risk Factors”, set forth in our 2020 Annual Report on Form 20-F.

***Comparison of the Three Months Ended September 30, 2021 and 2020 (unaudited):***

| | **Three Months Ended September 30,** | |
|---|---|---|
| | **2021** | **2020** |
| | **(EUR’000)** | |
| Revenue | 1,113 | 2,757 |
| Research and development costs | (58,761) | (64,059) |
| Selling, general and administrative expenses | (39,284) | (17,523) |
| **Operating profit / (loss)** | **(96,932)** | **(78,825)** |
| Share of profit / (loss) of associate | (3,855) | (3,101) |
| Finance income | 21,321 | 136 |
| Finance expenses | (877) | (39,970) |
| **Profit / (loss) before tax** | **(80,343)** | **(121,760)** |
| Tax on profit / (loss) for the period | (5) | 19 |
| **Net profit / (loss) for the period** | **(80,348)** | **(121,741)** |

***Revenue***

Revenue for the three months ended September 30, 2021 was €1.1 million, a decrease of €1.7 million, compared to €2.8 million for the three months ended September 30, 2020, and comprised sale of clinical supplies, rendering of services, and recognition of internal profit deferred from November 2018 when we entered into license agreements with VISEN. The decrease was primarily due to a lower sale of clinical supplies to VISEN compared to the same period last year.

### *Research and Development Costs*

Research and development costs were €58.8 million for the three months ended September 30, 2021, a decrease of €5.3 million, or 8%, compared to €64.1 million for the three months ended September 30, 2020.

External development costs related to TransCon hGH decreased by €20.0 million compared to the same period last year; however, including a €53.2 million reversal of pre-launch inventories, which had been recognized as research and development costs in current and previous periods. The reversal of pre-launch inventories resulted from the U.S. FDA approval of SKYTROFA (lonapegsomatropin-tcgd) on August 25, 2021. Disregarding the impact of the reversal of pre-launch inventories, higher external development costs related to TransCon hGH primarily reflect higher costs for manufacturing of product supply, but also higher costs for the ongoing clinical trials compared to the same period last year.

External development costs related to TransCon PTH increased by €0.9 million, primarily reflecting increased costs for clinical supplies and manufacturing, compared to the same period last year.

External development costs related to TransCon CNP increased by €9.7 million, primarily reflecting an increase in manufacturing costs, but also increases in clinical trial costs and clinical supplies.

External development costs related to our oncology product candidates, primarily TransCon TLR7/8 Agonist and TransCon IL-2 ß/g, increased by €2.6 million, reflecting an increase in costs for clinical trials and clinical supplies as these product candidates progress through the development stages and into manufacturing and clinical trials.

Other research and development costs increased by €1.5 million, primarily driven by an increase in personnel costs of €3.4 million and non-cash share-based payment of €0.5 million due to a higher number of employees in research and development functions. Facility costs increased by €1.9 million, whereas other costs allocated to research and development functions decreased by a total of €4.3 million, primarily relating to IT and professional fees.

Research and development costs included non-cash share-based payment of €7.5 million for the three months ended September 30, 2021, compared to €7.0 million for the three months ended September 30, 2020.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses were €39.3 million for the three months ended September 30, 2021, an increase of €21.8 million, or 125%, compared to €17.5 million for the three months ended September 30, 2020. The higher expenses were primarily due to an increase in personnel costs of €4.2 million and non-cash share-based payment of €2.4 million for additional commercial and administrative personnel, an increase in commercial costs of €4.9 million, and an increase in IT costs, including the implementation of a new enterprise resource planning system, of €4.1 million. Other costs allocated to selling, general and administrative functions increased by a total of €6.2 million, primarily reflecting increasing professional fees of €3.3 million, facility costs of €0.7 million and insurance costs of €1.1 million.

Selling, general and administrative expenses included non-cash share-based payment of €5.8 million for the three months ended September 30, 2021, compared to €3.4 million for the three months ended September 30, 2020.

### *Net Profit / (Loss) of Associate*

Net loss of associate was €3.9 million for the three months ended September 30, 2021, compared to a net loss of €3.1 million for the three months ended September 30, 2020. The net loss represents our share of net result from VISEN.

### *Finance Income and Finance Expenses*

Finance income was €21.3 million for the three months ended September 30, 2021 compared to €0.1 million for the three months ended September 30, 2020. Finance expenses were €0.9 million for the three months ended September 30, 2021 compared to €40.0 million for the same period in 2020. As we hold positions of marketable securities and cash and cash equivalents in U.S. Dollars, we are affected by exchange rate fluctuations when reporting our financial results in Euro. For the three months ended September 30, 2021, we recognized net exchange rate gains when reporting our U.S. Dollar positions in Euro, reflecting positive exchange rate fluctuations, compared to net exchange losses in the same period last year, reflecting negative exchange rate fluctuations.

We did not have any interest-bearing debt for any of the periods presented. However, we have accrued interest expenses on lease liabilities in accordance with IFRS 16, "Leases."

### *Tax for the Period*

Taxes for the three months ended September 30, 2021 as well as for the three months ended September 30, 2020 was zero. Taxes for the three months ended September 30, 2021 comprised an estimated tax credit of €0.2 million in the group of Danish companies, offset by a tax provision of €0.2 million in our German subsidiary.

***Comparison of the Nine Months Ended September 30, 2021 and 2020 (unaudited):***

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2021** | **2020** |
| | (EUR'000) | |
| Revenue | 2,881 | 6,418 |
| Research and development costs | (230,216) | (185,152) |
| Selling, general and administrative expenses | (111,876) | (56,243) |
| **Operating profit / (loss)** | **(339,211)** | **(234,977)** |
| Share of profit / (loss) in associates | 19,434 | (6,501) |
| Finance income | 44,589 | 1,677 |
| Finance expenses | (2,580) | (40,391) |
| **Profit / (loss) before tax** | **(277,768)** | **(280,192)** |
| Tax on profit / (loss) for the period | 253 | 202 |
| **Net profit / (loss) for the period** | **(277,515)** | **(279,990)** |

***Revenue***

Revenue for the nine months ended September 30, 2021 was €2.9 million, a decrease of €3.5 million, compared to €6.4 million for the nine months ended September 30, 2020, and comprised sale of clinical supplies, rendering of services, and recognition of internal profit deferred from November 2018 when we entered into license agreements with VISEN. The decrease was primarily due to lower sales of services and clinical supply to VISEN, partly offset by recognition of revenue from services rendered to another collaboration partner.

***Research and Development Costs***

Research and development costs were €230.2 million for the nine months ended September 30, 2021, an increase of €45.0 million, or 24%, compared to €185.2 million for the nine months ended September 30, 2020.

External development costs related to TransCon hGH increased by €0.4 million compared to the same period last year; however, including a €53.2 million reversal of pre-launch inventories which had been recognized as research and development costs in current and previous periods. The reversal of pre-launch inventories resulted from the U.S. FDA approval of TransCon hGH, known by its brand name SKYTROFA (lonapegsomatropin-tcgd), on August 25, 2021. Disregarding the impact on the reversal of pre-launch inventories, higher external development costs related to TransCon hGH primarily reflect higher costs for manufacturing of product supply, but also higher costs for the ongoing clinical trials compared to the same period of last year.

External development costs related to TransCon PTH increased by €4.0 million, primarily reflecting increased costs related to manufacturing of validation batches, device development, and increased costs for clinical trials and clinical supplies, compared to the same period last year.

External development costs related to TransCon CNP increased by €18.9 million, primarily reflecting an increase in clinical trial costs and clinical supplies, but also increased manufacturing costs.

External development costs related to our oncology product candidates, primarily TransCon TLR7/8 Agonist and TransCon IL-2 ß/g, increased by €9.4 million, reflecting increases in manufacturing costs, as well as increasing costs for clinical trials and clinical supplies as these product candidates progress through the development stages and into manufacturing and clinical trials.

Other research and development costs increased by €12.4 million, primarily driven by an increase in personnel costs of €11.7 million and non-cash share-based payment of €6.2 million due to a higher number of employees in research and development functions. Facility costs increased by €4.4 million, whereas IT costs decreased by €4.5 million and professional fees decreased by €2.3 million. Other costs allocated to research and development functions decreased by a total of €3.1 million, primarily relating to supplies and insurance costs.

Research and development costs included non-cash share-based payment of €30.3 million for the nine months ended September 30, 2021, compared to €24.1 million for the nine months ended September 30, 2020.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses were €111.9 million for the nine months ended September 30, 2021, an increase of €55.7 million, or 99%, compared to €56.2 million for the nine months ended September 30, 2020. The higher expenses were primarily due to an increase in personnel costs of €13.1 million and non-cash share-based payment of €7.7 million for additional commercial and administrative personnel, and an increase in IT costs of €14.7 million, primarily related to the implementation of a new enterprise resource planning system, an increase in costs related to building our commercial business of €6.6 million, and in professional fees of €6.5 million. Other costs allocated to selling, general and administrative functions increased by a total of €7.1 million, primarily reflecting increased insurance costs of €3.6 million and facility costs of €2.1 million.

Selling, general and administrative expenses included non-cash share-based payment of €22.4 million for the nine months ended September 30, 2021, compared to €14.7 million for the nine months ended September 30, 2020.

### *Net Profit / (Loss) of Associate*

Net profit of associate was €19.4 million for the nine months ended September 30, 2021, compared to a net loss of €6.5 million for the nine months ended September 30, 2020.

For the nine months ended September 30, 2021, the net profit of associate comprised a non-cash gain of €42.3 million as a result of the Series B financing in VISEN on January 8, 2021, and our share of loss of €22.9 million. The Series B financing did not change our accounting treatment of VISEN.

### *Finance Income and Finance Expenses*

Finance income was €44.6 million for the nine months ended September 30, 2021 compared to €1.7 million for the nine months ended September 30, 2020. Finance expenses were €2.6 million for the nine months ended September 30, 2021 compared to €40.4 million for the same period in 2020. As we hold positions of marketable securities and cash and cash equivalents in U.S. Dollar, we are affected by exchange rate fluctuations when reporting our financial results in Euro. For the nine months ended September 30, 2021, we recognized net exchange rate gains when reporting our U.S. Dollar positions in Euro, reflecting positive exchange rate fluctuations, compared to net exchange rate loses in the same period last year, reflecting negative exchange rate fluctuations.

We did not have any interest-bearing debt for any of the periods presented. However, we have accrued interest expenses on lease liabilities in accordance with IFRS 16, “Leases.”

### *Tax for the Period*

Taxes for the nine months ended September 30, 2021 was a net tax credit of €0.3 million compared to a net tax credit of €0.2 million for the nine months ended September 30, 2020. Taxes for the nine months ended September 30, 2021 comprised an estimated tax credit of €0.6 million in the group of Danish companies and a tax credit of €0.1 million in one of our U.S. subsidiaries, partly offset by a tax provision of €0.4 million in our German subsidiary.

## Liquidity and Capital Resources

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

As of September 30, 2021, these amounted to €929.9 million, and are specified as follows:

| | Carrying amount | Fair value |
|---|---|---|
| | (EUR’000) | |
| **September 30, 2021** | | |
| **Liquidity and capital resources** | | |
| Marketable securities | 236,961 | 236,898 |
| Cash and cash equivalents | 692,941 | 692,941 |
| **Total liquidity and capital resources** | **929,902** | **929,839** |
| **Classification in consolidated statement of financial position** | | |
| Non-current assets | 71,614 | 71,580 |
| Current assets | 858,288 | 858,259 |
| **Total liquidity and capital resources** | **929,902** | **929,839** |

Marketable securities have a weighted average duration of 6.1 and 17.6 months, for current (i.e., those maturing within twelve months after the reporting date) and non-current positions, respectively. The entire portfolio of marketable securities (current and non-current) has a weighted average duration of 9.6 months.

We have historically funded our operations primarily through issuance of preference shares, ordinary shares, including our initial public offering, follow-on offerings and exercise of warrants, convertible debt securities, and payments to us made under collaboration agreements.

In February 2015, we announced the closing of our initial public offering, with net proceeds of $111.5 million (or €101.4 million). In addition, we have completed follow-on public offerings of American Depositary Shares (“ADSs”) as specified below:

- In 2016, with net proceeds of $127.1 million (or €116.6 million);
- In 2017, with net proceeds of $145.2 million (or €123.1 million);
- In 2018, with net proceeds of $242.5 million (or €198.6 million);

- In 2019, with net proceeds of $539.4 million (or €480.3 million);
- In 2020, with net proceeds of $654.6 million (or €580.5 million); and
- In 2021, with net proceeds of $436.5 million (or €367.7 million).

Our expenditures are primarily related to research and development activities and general and administrative activities to support our therapeutic areas within endocrinology and oncology. In addition, expenditures relate to building our sales and marketing capabilities, and inventories, to support the launch of SKYTROFA (lonapegsomatropin-tcgd), as well as preparation for future product launches.

We manage our liquidity risk by maintaining adequate cash reserves and banking facilities, and by matching the maturity profiles of financial assets including marketable securities, with cash-forecasts including payment profiles on liabilities. We monitor the risk of a shortage of funds using a liquidity planning tool, to ensure sufficient funds are available to settle liabilities as they become due.

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities as of September 30, 2021, will be sufficient to meet our projected cash requirements for at least twelve months from the date of this report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including, but not limited to:

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

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, scale back or cease our research and development activities, preparing for potential commercialization, preclinical studies and clinical trials for our product candidates for which we retain such responsibility and our establishment and maintenance of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates. The following table summarizes our cash flows for each of the unaudited nine month periods ended September 30, 2021 and 2020:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| | (EUR'000) | |
| Cash flows from / (used in) operating activities | (294,339) | (181,216) |
| Cash flows from / (used in) investing activities | 1,344 | (220,067) |
| Cash flows from / (used in) financing activities | 372,016 | 592,336 |
| **Net increase / (decrease) in cash and cash equivalents** | **79,021** | **191,053** |

*Cash Flows from / (Used in) Operating Activities*

Net cash used in operating activities for the nine months ended September 30, 2021 was €294.3 million compared to €181.2 million for the nine months ended September 30, 2020.

The net loss for the nine months ended September 30, 2021 of €277.5 million included non-cash net financial income of €40.1 million, and tax charges of €0.5 million. In addition, net loss for the nine months ended September 30, 2021 included non-cash items of net €42.6 million, comprising share of profit of associate of €19.4 million, share-based payment charges of €52.7 million, depreciation and amortization of €11.1 million, and non-cash revenue of €1.7 million. The net change in working capital contributed negatively to cash flows by €18.8 million, primarily due to an increase in receivables and prepayments of €17.4 million, and inventories of €55.3 million, of which €53.2 million relates to reversal of write-down of pre-launch inventories, and a decrease in deferred income of €0.3 million, partly offset by an increase in trade payables and other payables of €54.3 million.

Net cash used in operating activities for the nine months ended September 30, 2020 was €181.2 million. The net loss for the nine months ended September 30, 2020 of €280.0 million included non-cash charges of €45.2 million, comprising share-based payment and depreciation, and non-cash net financial expenses and taxes, of €43.2 million. The net change in working capital contributed positively to cash flows by €10.4 million, primarily due to a net increase in trade payables and other payables of €20.7 million, partly offset by an increase in receivables and prepayments of €9.7 million and a decrease in deferred income of €0.6 million.

*Cash Flows from / (Used in) Investing Activities*

Cash flows from investing activities for the nine months ended September 30, 2021 of €1.3 million were related to acquisition of marketable securities of €87.5 million and settlement of marketable securities of €118.5 million, to the Series B investment in VISEN of €10.2 million, to acquisition of property, plant and equipment of €18.9 million, primarily related to leasehold improvements and equipment for use in the United States, and to acquisition of software of €0.5 million.

Cash flows used in investing activities for the nine months ended September 30, 2020 of €220.1 million were related to acquisition of marketable securities of €340.4 million and settlement of marketable securities of €132.7 million, to acquisition of property, plant and equipment of €11.7 million, primarily related to our oncology laboratories in the United States and for use in the laboratories of our German facility, and to acquisition of software of €0.7 million.

*Cash Flows from / (Used in) Financing Activities*

Cash flows from financing activities for the nine months ended September 30, 2021 of €372.0 million were comprised of €367.7 million in net proceeds from our follow-on public offering of ADSs completed in September 2021 and €9.2 million in net proceeds from warrant exercises in April, May, June, August and September 2021, partly offset by payments of principal portion of lease liabilities of €4.9 million.

Cash flows from financing activities for the nine months ended September 30, 2020 of €592.3 million were comprised of €580.5 million in net proceeds from our follow-on public offering of ADSs completed in July 2020 and €15.3 million in net proceeds from warrant exercises in April, May, June, August and September 2020, partly offset by payments on lease liabilities of €3.5 million.

**Off-balance Sheet Arrangements**

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

**Qualitative Disclosures about Market Risk**

Our activities expose us to the financial risks of changes in foreign currency exchange rates and interest rates. We do not enter into derivative financial instruments to manage our exposure to such risks. Further, we are exposed to credit risk and liquidity risk. For a description of our exposure to liquidity risks and processes for managing these risks, please refer to “Liquidity and Capital Resources”, set forth above.

*Foreign Currency Risk*

We are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the U.S. Dollar, the British Pound and the Danish Krone. We have received payments in U.S. Dollars under our collaborations, and the proceeds from our Series D financing in November 2014, our initial public offering in February 2015, and our follow-on offerings were in U.S. Dollars. We seek to minimize our exchange rate risk by maintaining cash positions in the currencies in which we expect to incur the majority of our future expenses and we make payments from those positions.

*Interest Rate Risk*

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

*Credit Risk*

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

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

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

For our receivables the credit risk is considered low and no provision for expected credit loss has been recognized.