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 April, 2023

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 333-228576, 333-203040, 333-210810, 333-211512, 333-213412, 333-214843, 333-216883, 333-254101, 333-261550 and 333-270088) 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Information Contained in this Form 6-K Report

Financial Statements

This report contains the Company's Unaudited Condensed Consolidated Interim Financial Statements as of and for the period ended March 31, 2023, including Management's Discussion and Analysis of Financial Condition and Results of Operations for the period presented therein.

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: April 27, 2023

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

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Unaudited Condensed Consolidated Interim Statements of Profit or Loss and Comprehensive Income / (Loss) for the Three Months Ended March 31, 2023 and 2022

	Notes	Three Months Ended March 31, 2023	2022
		(EUR'000)	
Consolidated Statement of Profit or Loss			
Revenue	**5**	33,589	6,828
Cost of sales		4,621	4,246
Gross profit		**28,968**	**2,582**
Research and development costs		106,114	83,193
Selling, general and administrative expenses		66,539	47,418
Operating profit / (loss)		**(143,685)**	**(128,029)**
Share of profit / (loss) of associate		(1,227)	(4,873)
Finance income		45,135	13,044
Finance expenses		9,840	5,399
Profit / (loss) before tax		**(109,617)**	**(125,257)**
Income taxes (expenses)		(1,297)	(241)
Net profit / (loss) for the period		**(110,914)**	**(125,498)**
Attributable to owners of the Company		(110,914)	(125,498)
Basic and diluted earnings / (loss) per share		€ (1.98)	€ (2.21)
Number of shares used for calculation (basic and diluted) [1]		56,091,927	56,720,063

	(EUR'000)	
Statement of Comprehensive Income		
Net profit / (loss) for the period	**(110,914)**	**(125,498)**
Other comprehensive income / (loss)		
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translating foreign operations	(787)	425
Other comprehensive income / (loss) for the period, net of tax	**(787)**	**425**
Total comprehensive income / (loss) for the period, net of tax	**(111,701)**	**(125,073)**
Attributable to owners of the Company	(111,701)	(125,073)

[1] As of March 31, 2023 and March 31, 2022, a total of 6,761,296 and 7,060,788 warrants outstanding, respectively, each carrying the right to subscribe for one ordinary share, and 575,000 convertible senior notes which can potentially be converted into 3,456,785 ordinary shares, can potentially dilute earnings per share in the future but have not been included in the calculation of diluted earnings per share because they are antidilutive for the periods presented.

Unaudited Condensed Consolidated Interim Statements of Financial Position

	Notes	March 31, 2023	December 31, 2022
		(EUR'000)	
Assets			
Non-current assets			
Intangible assets		4,717	4,828
Property, plant and equipment		127,762	129,095
Investment in associate		21,966	22,932
Other receivables	**10**	1,984	1,920
Marketable securities	**10**	—	7,492
		156,429	**166,267**
Current assets			
Inventories		150,850	130,673
Trade receivables	**10**	16,121	11,910
Income tax receivables		1,064	883
Other receivables	**10**	17,375	12,833
Prepayments		38,694	31,717
Marketable securities	**10**	84,460	290,688
Cash and cash equivalents	**10**	501,281	444,767
		809,845	**923,471**
Total assets		**966,274**	**1,089,738**
Equity and liabilities			
Equity			
Share capital	**8**	7,698	7,675
Distributable equity		159,503	255,673
Total equity		**167,201**	**263,348**
Non-current liabilities			
Borrowings	**10**	479,988	482,956
Derivative liabilities	**10**	116,768	157,950
Contract liabilities		3,956	14,213
		600,712	**655,119**
Current liabilities			
Borrowings	**10**	25,393	25,421
Contract liabilities		10,000	—
Trade payables and accrued expenses	**10**	131,438	101,032
Other liabilities		15,503	31,989
Income taxes payable		6,873	5,490
Provisions		9,154	7,339
		198,361	**171,271**
Total liabilities		**799,073**	**826,390**
Total equity and liabilities		**966,274**	**1,089,738**

Unaudited Condensed Consolidated Interim Statements of Changes in Equity

		Distributable Equity				
	Share Capital	Share Premium	Treasury Shares	Foreign Currency Translation Reserve	Accumulated Deficit	Total
			(EUR'000)			
Equity at January 1, 2023	**7,675**	**2,112,863**	**(149)**	**3,452**	**(1,860,493)**	**263,348**
Net profit / (loss) for the period	—	—	—	—	(110,914)	**(110,914)**
Other comprehensive income / (loss), net of tax	—	—	—	(787)	—	**(787)**
Total comprehensive income / (loss)	**—**	**—**	**—**	**(787)**	**(110,914)**	**(111,701)**
Transactions with Owners						
Share-based payment (Note 7)	—	—	—	—	13,688	**13,688**
Capital increase	23	1,843	—	—	—	**1,866**
Equity at March 31, 2023	**7,698**	**2,114,706**	**(149)**	**2,665**	**(1,957,719)**	**167,201**

		Distributable Equity				
	Share Capital	Share Premium	Treasury Shares	Foreign Currency Translation Reserve	Accumulated Deficit	Total
			(EUR'000)			
Equity at January 1, 2022	**7,646**	**2,107,739**	**(21)**	**3,779**	**(1,235,508)**	**883,635**
Net profit / (loss) for the period	—	—	—	—	(125,498)	**(125,498)**
Other comprehensive income / (loss), net of tax	—	—	—	425	—	**425**
Total comprehensive income / (loss)	**—**	**—**	**—**	**425**	**(125,498)**	**(125,073)**
Transactions with Owners						
Share-based payment (Note 7)	—	—	—	—	19,968	**19,968**
Acquisition of treasury shares (Note 9)	—	—	(134)	—	(105,965)	**(106,099)**
Capital increase	3	382	—	—	—	**385**
Equity at March 31, 2022	**7,649**	**2,108,121**	**(155)**	**4,204**	**(1,447,003)**	**672,816**

Unaudited Condensed Consolidated Interim Cash Flow Statements for the Three Months Ended March 31, 2023 and 2022

	Three Months Ended March 31,	
	2023	2022
	(EUR'000)	
Operating activities		
Net profit / (loss) for the period	**(110,914)**	**(125,498)**
Reversal of finance income	(45,135)	(13,044)
Reversal of finance expenses	9,840	5,399
Reversal of gain and loss on disposal of property, plant and equipment	21	—
Reversal of income taxes (expenses)	1,297	241
Increase / (decrease) in provisions	1,983	1,215
Adjustments for non-cash items:		
Non-cash consideration relating to revenue	(614)	(632)
Share of profit / (loss) of associate	1,227	4,873
Share-based payment	13,688	19,968
Depreciation	4,435	4,304
Amortization	111	111
Changes in working capital:		
Inventories	(20,178)	(17,031)
Receivables	(9,608)	(2,407)
Prepayments	(10,176)	(2,728)
Contract liabilities (deferred income)	(256)	(2,338)
Trade payables, accrued expenses and other payables	14,236	(4,338)
Cash flows generated from / (used in) operations	**(150,043)**	**(131,905)**
Finance income received	3,879	1,848
Finance expenses paid	(906)	(610)
Income taxes received / (paid)	26	(121)
Cash flows from / (used in) operating activities	**(147,044)**	**(130,788)**
Investing activities		
Acquisition of property, plant and equipment	(1,085)	(3,818)
Reimbursement from acquisition of property, plant and equipment	—	3,794
Purchase of marketable securities	—	(26,311)
Settlement of marketable securities	211,731	64,877
Cash flows from / (used in) investing activities	**210,646**	**38,542**
Financing activities		
Payment of principal portion of lease liabilities	(2,568)	(1,950)
Net proceeds from convertible senior notes	—	504,454
Proceeds from exercise of warrants	1,866	385
Acquisition of treasury shares, net of transaction costs	—	(105,154)
Cash flows from / (used in) financing activities	**(702)**	**397,735**
Increase / (decrease) in cash and cash equivalents	**62,900**	**305,489**
Cash and cash equivalents at January 1	444,767	446,267
Effect of exchange rate changes on balances held in foreign currencies	(6,386)	3,887
Cash and cash equivalents at March 31	**501,281**	**755,643**
Cash and cash equivalents include:		
Bank deposits	501,281	754,497
Short-term marketable securities	—	1,146
Cash and cash equivalents at March 31	**501,281**	**755,643**

Note 1—General Information

Ascendis Pharma A/S, together with its subsidiaries, is applying its innovative TransCon technologies to build a leading, fully integrated, global, biopharma 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 (the "Board") approved these unaudited condensed consolidated interim financial statements on April 27, 2023.

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, 2022, and accompanying notes, which have been prepared in accordance with IFRS as issued by the International Accounting Standards Board (the "IASB") and as adopted by the European Union (the "EU").

The accounting policies applied are consistent with those of the previous financial year. A description of the accounting policies is provided in the Accounting Policies section of the audited consolidated financial statements as of and for the year ended December 31, 2022.

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, "Significant Accounting Judgements and Estimates."

New International Financial Reporting Standards Not Yet Effective

The IASB has issued a number of new or amended standards, which have not yet become effective or have not yet been adopted by the EU. Therefore, these new standards have not been incorporated in these unaudited condensed consolidated interim financial statements.

Amendments to IAS 1, "Classification of Liabilities as Current or Non-current"

In January 2020, the IASB issued amendments to paragraphs 69 to 76 of IAS 1, "Presentation of Financial Statements," to specify the requirements for classifying liabilities as current or non-current. The amendments clarify:

- What is meant by a right to defer settlement;
- That a right to defer must exist at the end of the reporting period;
- That classification is unaffected by the likelihood that an entity will exercise its deferral right; and
- That only if an embedded derivative in a convertible liability is itself an equity instrument would the terms of a liability not impact its classification.

If approved by the EU, the amendments are effective for annual reporting periods beginning on or after January 1, 2024, and must be applied retrospectively. The amendments are expected to require the convertible notes (presented as part of borrowings on the statement of financial position) and derivative liabilities, both presented as non-current liabilities at March 31, 2023, to be presented as current liabilities.

On March 31, 2023, the carrying amount of convertible notes and derivative liabilities were €399.9 million and €116.8 million, respectively.

The consolidated financial statements are not expected to be affected by other new or amended standards.

Note 3—Significant Accounting Judgements and Estimates

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

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, 2022.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized prospectively. While the application of critical accounting estimates is subject to material estimation uncertainties, management's ongoing revisions of critical accounting estimates and underlying assumptions have not revealed any material impact in any of the periods presented in the unaudited condensed consolidated interim financial statements. Additionally, there have been no other changes to the application of significant accounting judgements, or estimation uncertainties regarding accounting estimates compared to December 31, 2022.

Note 4—Significant Events in the Reporting Period

Global Banking Situation

In March 2023, the Federal Deposit Insurance Corporation (the "FDIC") announced that Silicon Valley Bank ("SVB") had been closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. The Company did not hold deposits or securities or maintain any accounts at SVB. Following the closure of SVB and subsequent developments in the global banking sector, the Company considered the risk of expected credit loss on bank deposits and marketable securities, including the hypothetical impact arising from the probability of default, which is considered in conjunction with the expected loss caused by default by banks or securities with similar credit-ratings and attributes.

In line with previous periods, this assessment did not reveal a material impairment loss, and accordingly no provision for expected credit loss has been recognized.

Conflict in the Region Surrounding Ukraine and Russia

The ongoing conflict in the region surrounding Ukraine and Russia has impacted our ability to continue clinical trial activities in those countries. The conflict did not have a direct material impact on the unaudited condensed consolidated interim financial statements.

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.

COVID-19 did not have a direct material impact on the unaudited condensed consolidated interim financial statements.

Note 5—Revenue

Revenue from commercial sale of products relates to sale of SKYTROFA® (lonapegsomatropin-tcgd) on the U.S. market, which is sold to specialty pharmacies and a specialty distributor ("commercial customers"). Customer payment terms are typically 30 days from the transaction date. SKYTROFA was approved by the U.S. Food and Drug Administration in August 2021, and the Company began shipping products to commercial customers in the fourth quarter of 2021.

Other revenue is generated primarily from three license agreements, which were entered into in 2018. The licenses grant VISEN Pharmaceuticals exclusive rights to develop and commercialize TransCon hGH, TransCon PTH and TransCon CNP in Greater China.

	Three Months Ended March 31,	
	2023	2022
	(EUR'000)	
Revenue from external customers		
Commercial sale of products	31,551	1,888
Rendering of services	1,170	372
Sale of clinical supply	254	3,936
Licenses	614	632
Total revenue from external customers	**33,589**	**6,828**
Attributable to		
Commercial customers	31,551	1,888
Collaboration partners and license agreements	2,038	4,940
Total revenue from external customers	**33,589**	**6,828**
Specified by timing of recognition		
Recognized over time	1,170	372
Recognized at a point in time	32,419	6,456
Total revenue from external customers	**33,589**	**6,828**
Revenue by geographical location		
Europe	—	135
North America	33,070	6,456
China	519	237
Total revenue from external customers	**33,589**	**6,828**

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—Share-based Payment

As an incentive to the senior management and the Executive Board, other employees, members of the Board and select consultants, Ascendis Pharma A/S has established warrant programs, a Restricted Stock Unit ("RSU") program adopted in December 2021, and a Performance Stock Unit ("PSU") Program adopted in February 2023, which are all classified as equity-settled share-based payment transactions.

Share-based Compensation Costs

Share-based compensation costs are determined using the grant date fair value and are recognized over the vesting period as research and development costs, selling, general and administrative expenses, or cost of sales. For the three months ended March 31, 2023 and 2022, share-based compensation costs recognized in the unaudited condensed consolidated interim statement of profit or loss were €13.7 and €20.0 million, respectively.

Restricted Stock Unit Program

RSUs are granted by the Board to certain members of senior management and the Executive Board, certain other employees and certain members of the Board ("RSU-holders"). In addition, RSUs may be granted to select consultants.

One RSU represents a right for the RSU-holder to receive one ADS of Ascendis Pharma A/S upon vesting, if the vesting conditions are met. RSUs granted vest over three years with 1/3 of the RSUs vesting on each anniversary date from the date of grant, and require RSU-holders to be employed, or provide a specified period of service ("service conditions").

Performance Stock Unit Program

PSUs are granted by the Board to certain members of senior management and the Executive Board ("PSU-holders"). In addition, PSUs may be granted to other employees, select consultants and members of the Board. PSUs were granted for the first time in March 2023.

One PSU represents a right for the PSU-holder to receive one ADS of Ascendis Pharma A/S upon vesting. PSUs vest in a manner similar to the service conditions of the RSUs; however, vesting is also contingent upon achievement of performance target goals as determined by the Board, provided that no more than 10% of each tranche may be directly attributable to accomplishment of financial results achieved in the financial year prior to the vesting date. Exceeding performance target goals will not result in granting of additional ADSs.

RSUs and PSUs generally cease to vest from the date of termination of employment or board membership, as applicable, whereas unvested RSUs or PSUs will forfeit. The Board may at its discretion and on an individual basis decide to deviate from the vesting conditions, including deciding to accelerate vesting in the event of termination of employment or board membership, as applicable.

All RSUs and PSUs are settled at the time of vesting by treasury shares that are ADSs repurchased in the market. The Company may at its sole discretion choose to make a cash settlement instead of delivering ADSs.

RSU and PSU Activity

The following table specifies the number of RSUs and PSUs granted and outstanding at March 31, 2023:

	Restricted Stock Units	Performance Stock Units	Total
Outstanding		(Number)	
January 1, 2023	82,492	—	82,492
Granted during the period	609,695	112,268	721,963
Forfeited during the period	(10,494)	—	(10,494)
March 31, 2023	**681,693**	**112,268**	**793,961**
Specified by vesting year			
2023	41,240	—	41,240
2024	240,888	37,422	278,310
2025	199,757	37,423	237,180
2026	199,808	37,423	237,231
March 31, 2023	**681,693**	**112,268**	**793,961**

Warrant Program

Warrants are granted by the Board in accordance with authorizations given to it by the shareholders of Ascendis Pharma A/S to all employees, members of the Board and select consultants. 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 at the time of grant as determined by the Board. Vested warrants may be exercised in two or four annual exercise periods.

Warrant Activity

The following table specifies the warrant activity for the three months ended March 31, 2023:

	Total Warrants	Weighted Average Exercise Price
	(Number)	(EUR)
Outstanding		
January 1, 2023	6,864,011	81.30
Granted during the period	113,585	103.60
Exercised during the period	(176,253)	10.40
Forfeited during the period	(40,047)	118.69
March 31, 2023	**6,761,296**	**83.30**
Vested at March 31, 2023	**5,013,862**	**70.58**

The exercise prices of outstanding warrants under the Company's warrant programs range from €6.48 to €145.50 depending on the grant dates.

Note 8—Share Capital

The share capital of Ascendis Pharma A/S consists of 57,328,548 fully paid shares at a nominal value of DKK 1, all in the same share class.

Note 9—Treasury Shares

The holding of treasury shares is as follows:

	Nominal values	Holding	Holding in % of total outstanding shares
	(EUR'000)	(Number)	
Treasury shares			
January 1, 2023	149	1,113,152	2.0%
March 31, 2023	**149**	**1,113,152**	**1.9%**

Note 10—Financial Assets and Liabilities

Financial assets and liabilities comprise the following:

	March 31, 2023	December 31, 2022
	(EUR'000)	
Financial assets by category		
Trade receivables	16,121	11,910
Other receivables (excluding income tax and indirect tax receivables)	8,464	3,884
Marketable securities	84,460	298,180
Cash and cash equivalents	501,281	444,767
Financial assets measured at amortized cost	**610,326**	**758,741**
Total financial assets	**610,326**	**758,741**
Classified in the statement of financial position		
Non-current assets	1,984	9,412
Current assets	608,342	749,329
Total financial assets	**610,326**	**758,741**
Financial liabilities by category		
Borrowings		
Convertible senior notes	399,880	399,186
Lease liabilities	105,501	109,191
Trade payables and accrued expenses	131,438	101,032
Financial liabilities measured at amortized cost	**636,819**	**609,409**
Derivative liabilities	116,768	157,950
Financial liabilities measured at fair value through profit or loss	**116,768**	157,950
Total financial liabilities	**753,587**	**767,359**
Classified in the statement of financial position		
Non-current liabilities	596,756	640,907
Current liabilities	156,831	126,452
Total financial liabilities	**753,587**	**767,359**

Marketable Securities

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

	March 31, 2023	December 31, 2022
	(EUR'000)	
Marketable securities		
U.S. Treasury bills	—	79,086
U.S. Government bonds	42,955	99,337
Corporate bonds	36,907	104,236
Agency bonds	4,598	15,521
Total marketable securities	**84,460**	**298,180**
Classified based on maturity profiles		
Non-current assets	—	7,492
Current assets	84,460	290,688
Total marketable securities	**84,460**	**298,180**
Specified by rate structure		
Fixed rate	75,834	205,825
Floating rate	8,626	11,787
Zero-coupon	—	80,568
Total marketable securities	**84,460**	**298,180**
Specified by investment grade credit rating		
High grade	51,052	203,530
Upper medium grade	33,408	94,650
Total marketable securities	**84,460**	**298,180**

The portfolio of marketable securities is all denominated in U.S. Dollars. At March 31, 2023, the portfolio had a weighted average duration of 3.4 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.

Convertible Senior Notes

In March 2022, the Company issued an aggregate principal amount of $575.0 million of fixed rate 2.25% convertible notes. The net proceeds from the offering of the convertible notes were $557.9 million (€503.3 million) after deducting the initial purchasers' discounts and commissions and offering expenses. The convertible notes rank equally in right of payment with all future senior unsecured indebtedness. Unless earlier converted or redeemed, the convertible notes will mature on April 1, 2028.

The convertible notes accrue interest at a rate of 2.25% per annum, payable semi-annually in arrears on April 1 and October 1 of each year. At any time before the close of business on the second scheduled trading day immediately before the maturity date, noteholders may convert their convertible notes at their option into the Company's ordinary shares represented by ADSs, together, if applicable, with cash in lieu of any fractional ADS, at the then-applicable conversion rate. The initial conversion rate is 6.0118 ADSs per $1,000 principal amount of convertible notes, which represents an initial conversion price of $166.34 per ADS. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events.

The convertible notes will be optionally redeemable, in whole or in part (subject to certain limitations), at the Company's option at any time, and from time to time, on or after April 7, 2025, but only if the last reported sale price per ADS exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related optional redemption notice; and (ii) the trading day immediately before the date the Company sends such notice.

On March 31, 2023, the carrying amount of the convertible notes was €399.9 million, and the fair value was approximately €388.0 million. Fair value cannot be measured based on quoted prices in active markets or other observable input, and accordingly the fair value was measured by using an estimated market rate for an equivalent non-convertible instrument.

Derivative Liabilities

Derivative liabilities relate to the foreign currency conversion option embedded in the convertible notes.

Fair value cannot be measured based on quoted prices in active markets or other observable inputs, and accordingly, derivative liabilities are measured by using the Black-Scholes option pricing model. Fair value of the option is calculated, applying the following assumptions: (1) conversion price; (2) the Company's share price; (3) maturity of the option; (4) a risk-free interest rate equaling the effective interest rate on a U.S. government bond with the same lifetime as the maturity of the option; (5) no payment of dividends; and (6) an expected volatility using the Company's share price (49% as of March 31, 2023).

For additional description of fair values, refer to the following section "Fair Value Measurement."

Sensitivity Analysis

On March 31, 2023, all other inputs and assumptions held constant, a 10% relative increase in volatility, will increase the fair value of derivative liabilities by approximately €14.0 million and indicates a decrease in profit or loss and equity before tax. Similarly, a 10% relative decrease in volatility indicates the opposite impact.

Similarly, on March 31, 2023, all other inputs and assumptions held constant, a 10% increase in the share price, will increase the fair value of derivative liabilities by approximately €21.8 million and indicates a decrease in profit or loss and equity before tax. Similarly, a 10% decrease in the share price indicates the opposite impact.

Fair Value Measurement

Derivative liabilities are measured at fair value. All other financial assets and liabilities are measured at amortized cost.

Because of the short-term maturity for cash and cash equivalents, receivables and trade payables, their fair value approximate their carrying amount. Fair value compared to carrying amount of marketable securities, convertible notes and derivatives and their level in the fair value hierarchy is summarized in the following table, where:

Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date;

Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and

Level 3 inputs are unobservable inputs for the asset or liability.

	March 31, 2023		December 31, 2022		
	Carrying amount	Fair value	Carrying amount	Fair value	Fair value level
	(EUR'000)				(1-3)
Financial assets					
Marketable securities	84,460	83,525	298,180	295,843	1
Financial assets measured at amortized cost	**84,460**	**83,525**	**298,180**	**295,843**	
Total financial assets	**84,460**	**83,525**	**298,180**	**295,843**	
Financial liabilities					
Convertible senior notes	399,880	388,003	399,186	382,459	3
Financial liabilities measured at amortized cost	**399,880**	**388,003**	**399,186**	**382,459**	
Derivative liabilities	116,768	116,768	157,950	157,950	3
Financial liabilities measured at fair value through profit or loss	**116,768**	**116,768**	**157,950**	**157,950**	
Total financial liabilities	**516,648**	**504,771**	**557,136**	**540,409**	

Movements in level 3 fair value measurements are specified below:

	2023	2022
	(EUR'000)	
Derivative liabilities		
January 1	157,950	—
Additions	—	142,467
Remeasurement recognized in financial (income) or expense	(41,182)	(1,088)
March 31	**116,768**	**141,379**

Maturity Analysis

Maturity analysis (on an undiscounted basis) for non-derivative financial liabilities recognized in the unaudited condensed consolidated statements of financial position at March 31, 2023, is specified below:

	< 1 year	1-5 years	>5 years	Total contractual cash-flows	Carrying amount
			(EUR'000)		
Financial liabilities					
March 31, 2023					
Borrowings					
Convertible senior notes	11,897	41,638	534,684	588,219	399,880
Lease liabilities	13,565	51,967	57,331	122,863	105,501
Trade payables and accrued expenses	131,438	—	—	131,438	131,438
Total financial liabilities	**156,900**	**93,605**	**592,015**	**842,520**	**636,819**

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, 2022 – "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 condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are predictions or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the timing or likelihood of regulatory filings and approvals for our product candidates, including the possibility of a delay in the FDA's final regulatory decision on the TransCon PTH New Drug Application ("NDA");
- our expectations regarding the commercial availability of TransCon Growth Hormone ("TransCon hGH"), known by its brand name SKYTROFA® (lonapegsomatropin-tcgd), in the United States and related patient support services;
- the commercialization of our products and product candidates, if approved;
- our commercialization, marketing and manufacturing capabilities of our products and 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 pursuit of Ophthalmology as our third of three independent therapeutic areas of focus and our development of a pipeline of product candidates related to Ophthalmology;
- our expectations regarding the potential market opportunities and patient populations for our products and product candidates, if approved for commercial use;
- our expectations regarding the potential advantages of our products and product candidates over existing therapies;
- our 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 submit INDs or similar for such product candidates;
- our development plans with respect to our products and product candidates;
- our pursuit of additional indications for TransCon hGH;

- 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, our products and product candidates and technologies, including global commercialization strategies;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products and product candidates;
- our expectations regarding our ability to apply our technology platform and algorithm for product innovation to develop highly differentiated product candidates to address unmet medical needs;
- our ability to apply our platform technology to build a leading, fully integrated, global biopharmaceutical company;
- our use of our TransCon technologies to create new and potentially best-in-class therapies;
- 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;
- the impact of international economic, political, legal, compliance, social and business factors, including inflation; and
- the effects on our business of the global banking situation, worldwide COVID-19 pandemic and the ongoing conflict in the region surrounding Ukraine and Russia.

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, 2022 — "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 technology platform to build a leading, fully integrated, global biopharma company focused on making a meaningful difference in patients' lives. Guided by our core values of patients, science, and passion, we use our TransCon technologies to create new and potentially best-in-class therapies.

Our Vision

In January 2019, we announced Vision 3x3, our strategic roadmap through 2025 to build a leading fully integrated, global, biopharma company and achieve sustainable growth through multiple approaches:

- Obtain regulatory approval for three independent Endocrinology Rare Disease products:
  - TransCon hGH for pediatric growth hormone deficiency
  - TransCon PTH for adult hypoparathyroidism
  - TransCon CNP for achondroplasia
- Grow Endocrinology Rare Disease pipeline through:
  - Global clinical reach
  - Pursuing 9 total indications, label optimization, and life cycle management
  - New endocrinology products
- Establish global commercial presence for our Endocrinology Rare Disease area:
  - Build integrated commercial organization in North America and select European countries
  - Establish global commercial presence through partners with local expertise and infrastructure
- Advance a high-value oncology pipeline with one investigational new drug ("IND") or similar submission each year
- Create a third independent therapeutic area with a diversified pipeline.

We have applied our TransCon technology platform in combination with clinically validated parent drugs or pathways using our algorithm for product innovation, with the goal of creating product candidates with the potential for best-in-class safety, efficacy, tolerability, and convenience in our therapeutic areas of Endocrinology Rare Diseases, Oncology, and Ophthalmology. We plan to apply this algorithm for product innovation in additional therapeutic areas. We believe our approach to product innovation may reduce the risks associated with traditional drug development, and that our TransCon technology platform has been validated by non-clinical and clinical programs completed to date.

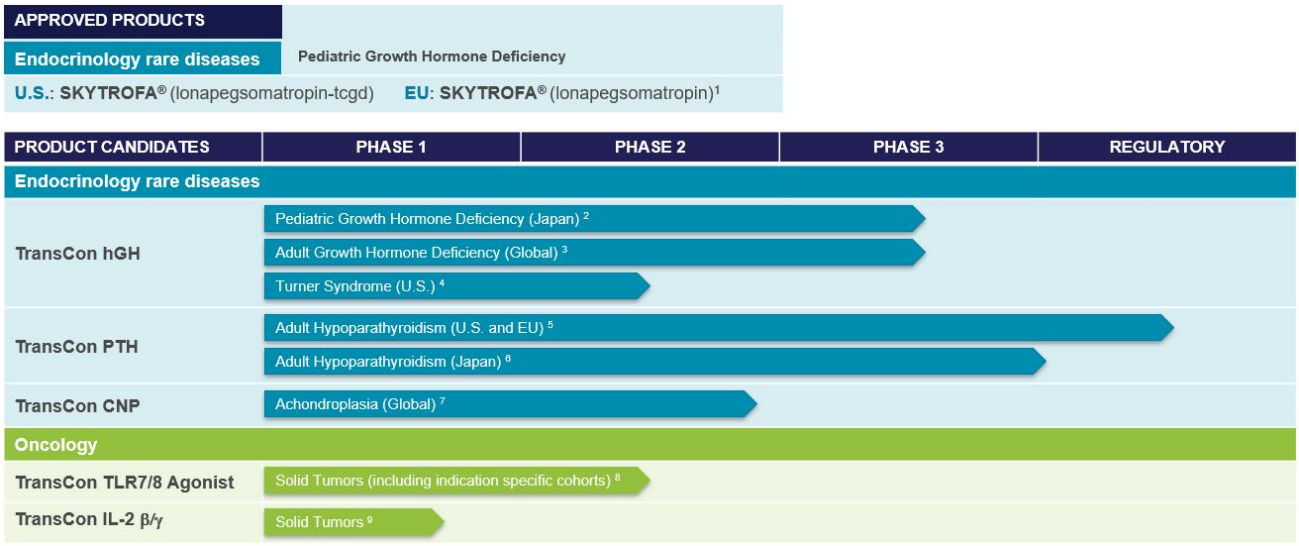
Ascendis Algorithm for Product Innovation

When we apply our TransCon technology platform to clinically validated parent drugs or pathways, we may benefit from established clinical safety and efficacy data, which we believe increases the probability of success compared to traditional drug development. As presented in the graphic below, our algorithm for product innovation focuses on identifying indications that have an unmet medical need, have a clinically validated parent drug or pathway, are suitable to our TransCon technologies, have potential for creating a clearly differentiated product, have a potential established development pathway, and have the potential to address a large market.

TransCon Products and Product Candidates Pipeline

We currently have one marketed product and a diversified portfolio of product candidates in clinical development in the areas of Endocrinology Rare Diseases and Oncology. We are also working to apply our TransCon technology platform in additional therapeutic areas, including Ophthalmology.

- *First Marketed Product* – Our first marketed product is SKYTROFA® (lonapegsomatropin-tcgd), developed as TransCon Growth Hormone ("TransCon hGH"), which has received regulatory approval in the United States for the treatment of pediatric patients one year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone, also known as growth hormone deficiency ("GHD"). SKYTROFA is now commercially available for prescription in the United States. In the European Union ("EU"), we received marketing authorization for TransCon hGH – known by its brand name SKYTROFA (lonapegsomatropin) – from the European Commission ("EC") as a once-weekly subcutaneous injection for the treatment of children and adolescents ages 3 to 18 years with growth failure due to insufficient secretion of endogenous growth hormone. We plan to commercially launch SKYTROFA in Germany during the third quarter of 2023.
- *Endocrinology Rare Disease Pipeline* – We are developing three product candidates in our Endocrinology Rare Disease portfolio, spanning five potential indications across multiple geographies. These include TransCon hGH for pediatric GHD, adult GHD, and Turner Syndrome; TransCon PTH for hypoparathyroidism; and TransCon CNP for achondroplasia ("ACH").
- *Oncology* – We have initiated clinical development of two immuno-oncology product candidates: TransCon TLR7/8 Agonist, an investigational, long-acting prodrug of resiquimod, a small molecule agonist of Toll like receptors ("TLR") 7 and 8 for intratumoral delivery and TransCon IL-2 ß/g for systemic delivery, designed to provide prolonged exposure to an IL-2 variant that selectively activates the IL-2Rß/g, with minimal binding to IL-2Rα. Our clinical development program for these product candidates also includes evaluation of them as a potential combination therapy.
- *Ophthalmology* – In January 2023, we announced Ophthalmology as our third independent therapeutic area. TransCon RBZ (ranibizumab) is our first investigational pipeline candidate in this therapeutic area, being developed to address vision loss caused by abnormal blood vessel growth and/or fluid build-up in the back of the eye. Our Ophthalmology R&D pipeline includes other opportunities in early stages of development.



1. *Not yet marketed in the EU*
2. *riGHt Trial*
3. *foresiGHt Trial*
4. *New InsiGHts Trial*
5. *NDA submitted to the FDA, PDUFA action date April 30, 2023 – for additional discussion of recent developments with the FDA see TransCon Product Candidates – Endocrinology Rare Diseases – TransCon PTH – Clinical Development of TransCon PTH for Adult Hypoparathyroidism; EU MAA submitted November 2022, decision anticipated Q4 2023*
6. *PaTHway Japan Trial*
7. *ApproaCH Trial*
8. *transcendIT-101 Trial, including 4 indication-specific cohorts currently enrolling patients*
9. *IL-Believe Trial*

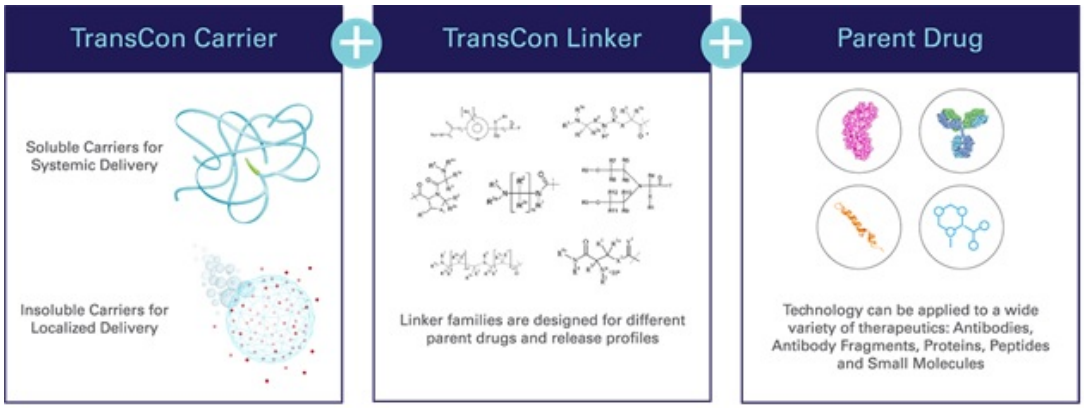
Global Commercialization Strategy

We are establishing a global presence to commercialize approved TransCon products. In the U.S., we have established a multi-faceted organization to support the ongoing commercialization of SKYTROFA. This organization will also serve as the foundation for future Endocrinology Rare Disease product launches in the U.S. We are expanding our presence in Europe by building integrated organizations in select countries, beginning with the planned launch of SKYTROFA in Germany, and through established distribution channels in other countries. In other markets, we plan to establish commercial presence through partners with local expertise and infrastructure.

TransCon Technology Platform

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

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



TransCon Products – Endocrinology Rare Diseases

TransCon Growth Hormone (hGH) for Pediatric Growth Hormone Deficiency

TransCon hGH is a prodrug of somatropin ("hGH") composed of an unmodified somatropin, administered once weekly, that is transiently bound to a carrier and proprietary linker. TransCon hGH is designed to maintain the same mode of action as daily therapies by releasing the same recombinant growth hormone molecule, somatropin, as used in extensively proven daily hGH therapy.

In August 2021, the FDA approved TransCon hGH, known by its brand name SKYTROFA, for the treatment of pediatric patients one year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone, also known as GHD. SKYTROFA is the first FDA approved product that delivers somatropin, or growth hormone, by sustained release over one week.

In January 2022, the EC granted marketing authorization for SKYTROFA (developed under the name TransCon hGH) as a once-weekly subcutaneous injection for the treatment of children and adolescents ages 3 to 18 years with growth failure due to insufficient secretion of endogenous growth hormone.

In March 2023, we enrolled our first patient in SkybriGHt, a Phase 4 U.S. multi-center, non-interventional, observational cohort study of subjects treated with SKYTROFA in the post-marketing setting.

TransCon Product Candidates – Endocrinology Rare Diseases

TransCon Growth Hormone (hGH) for Other Indications

Clinical Development in Adults

We are currently conducting foresiGHt, a global Phase 3 trial investigating the metabolic benefits of TransCon hGH in adults with GHD. Patients in the trial are randomized in a 1:1:1 ratio into the three arms of the study—treatment with once-weekly TransCon hGH, once-weekly placebo, or daily hGH. The primary endpoint of the trial is a change from baseline in percentage trunk fat at 38 weeks. Following the 38-week main trial period, all patients will be eligible to receive once-weekly TransCon hGH during the 52-week open-label extension. During the fourth quarter of 2022, we completed recruitment into this trial, and topline results are expected in the fourth quarter of 2023.

Other Development Plans

In June 2022, we submitted a trial protocol to the FDA for New InsiGHTS, a Phase 2 trial to evaluate TransCon hGH in Turner Syndrome. We expect to complete enrollment in the third quarter of 2023. Based on the nature of Turner Syndrome, in this trial we are evaluating higher doses of TransCon hGH and daily hGH compared to doses studied for GHD. In addition, we are also considering other potential indications for TransCon hGH where we believe a long-acting hGH therapy may offer benefits to patients.

TransCon PTH

TransCon PTH (palopegteriparatide) is an investigational prodrug of parathyroid hormone composed of PTH(1-34) transiently conjugated to an inert carrier via a TransCon linker that is designed to be dosed once-daily to achieve and maintain a steady concentration of PTH in the bloodstream within the normal range, at levels similar to those observed in healthy individuals. TransCon PTH is designed to restore physiologic levels of PTH, 24 hours per day, thereby more fully addressing all aspects of the disease including normalizing serum and urinary calcium and serum phosphate levels. Pharmacokinetic data from our multiple ascending dose cohorts in our Phase 1 trial of TransCon PTH in healthy subjects demonstrated a half-life of approximately 60 hours, supporting an infusion-like profile with daily administration. We believe TransCon PTH can address the fundamental limitations of short-acting PTH molecules and become a highly differentiated therapy for hypoparathyroidism.

Clinical Development of TransCon PTH for Adult Hypoparathyroidism

Our ongoing Phase 3 PaTHway Trial, Phase 3 PaTHway Japan Trial, and Phase 2 PaTH Forward Trial evaluated TransCon PTH in adult patients with hypoparathyroidism. Following the primary outcome period, all three trials continue in the extension portion to collect long term data.

On April 3, 2023, we announced that the FDA has notified us that, as part of their ongoing review, the FDA has identified deficiencies in our NDA for TransCon PTH in hypoparathyroidism that at the time precludes them from holding further discussions about labeling and post-marketing requirements/commitments. The deficiencies were not disclosed in the letter. The FDA also stated that this does not reflect their final regulatory decision on our application. The FDA originally accepted for Priority Review our NDA in October 2022 and set a Prescription Drug User Fee Act (“PDUFA”) target action date of April 30, 2023. This development a month from the PDUFA action date may lead to a delay in the FDA’s final regulatory decision on the TransCon PTH NDA.

On April 3, 2023, we also announced that we received the comprehensive Day 120 response from the European Medicines Agency (“EMA”). We remain on track for a EC decision on the Marketing Authorisation Application (“MAA”) for TransCon PTH during the fourth quarter of 2023. If approved, first launch planned in Germany in early 2024.

During the second quarter of 2023, we submitted an application to German regulatory authorities to initiate an early access program in Germany. If approved, we expect to enroll first patient during the second quarter of 2023.

In January 2023, we announced topline data from PaTHway Japan, a single-arm Phase 3 trial to evaluate the safety, tolerability, and efficacy of TransCon PTH in adults with hypoparathyroidism. The study achieved its primary objective, with topline results consistent with our trials in North America and the EU. Twelve out of thirteen patients met the primary composite endpoint, which was defined as serum calcium levels in the normal range (8.3–10.6 mg/dL) and independence from conventional therapy (active vitamin D and >600 mg/day of calcium supplements). In this trial, TransCon PTH was generally well-tolerated, with no discontinuations related to study drug. Twelve patients continue in the ongoing 3-year extension portion of the PaTHway Japan Trial.

In December 2022, the FDA allowed Ascendis to initiate a U.S. expanded access program (“EAP”) for TransCon PTH for eligible adult patients with hypoparathyroidism with prior PTH treatment experience. This EAP is open for enrollment, allows U.S. physicians to request access to investigational TransCon PTH for their eligible patients.

In November 2022, we submitted a MAA to the EMA for TransCon PTH in adult patients with hypoparathyroidism.

In September 2022, we announced new Week 110 data from the Phase 2 PaTH Forward Trial showing that long-term therapy with TransCon PTH provided a durable response in adult patients with hypoparathyroidism, as evidenced by continued normalization of mean serum calcium levels and 93% of patients achieving independence from conventional therapy with active vitamin D and therapeutic levels of calcium. As of March 31, 2023, 57 out of the 59 patients continued in the open-label extension (“OLE”) portion of the trial, where they receive a customized maintenance dose of TransCon PTH. In addition, all 57 subjects have exceeded three years of follow-up in the PaTH Forward Trial. Two patients withdrew from the trial for reasons unrelated to safety or efficacy of the study drug.

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

Following an initial blinded study period of 26 weeks, all 79 patients completing the blinded period opted to receive treatment with TransCon PTH in the ongoing open-label extension portion of the study for up to 3 years (156 weeks). As of March 31, 2023, 76 out of 79 patients have exceeded two years of follow-up in the PaTHway Trial.

TransCon CNP

TransCon CNP is an investigational long-acting prodrug of C-type natriuretic peptide designed to provide continuous CNP exposure at therapeutic levels with a well-tolerated and convenient once-weekly dose. It is being developed for the treatment of children with ACH. 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. Shorter-acting CNP and CNP analogs in development have resulted in high C_{max} levels that may cause adverse cardiovascular events. We believe the therapeutically sustained release of TransCon CNP offers advantages that may mitigate this issue, leading to more constant CNP exposure at lower C_{max} to correlate with better therapeutic outcomes.

Clinical Development of TransCon CNP for Achondroplasia

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

In November 2022, we announced topline results from ACcomplisH, a Phase 2 randomized, double-blind, placebo-controlled, dose-escalation trial evaluating the safety and efficacy of once-weekly TransCon CNP compared to placebo.

The ACcomplisH Trial evaluated 57 children with ACH aged 2 to 10 years old, randomized in a 3:1 ratio to receive either sequential ascending doses of once-weekly TransCon CNP or placebo for 52 weeks. The trial met its primary objectives, demonstrating that TransCon CNP at 100 µg/kg/week met the primary efficacy endpoint of annualized height velocity ("AHV") at 52 weeks (p=0.0218). All 57 randomized children completed the blinded portion of ACcomplisH and continued in the OLE portion of ACcomplisH at the 100 µg/kg/week dose. As of March 31, 2023, 57 out of 57 children continued in the OLE.

TransCon CNP Dose Group (n)	**AHV (cm/year)** LS Mean [95% CI]	**p-value** (TransCon CNP vs. Pooled Placebo)
6 µg/kg/week (n=10)	**4.09** [3.34, 4.84]	0.6004
20 µg/kg/week (n=11)	**4.52** [3.82, 5.22]	0.7022
50 µg/kg/week (n=10)	**5.16** [4.43, 5.90]	0.0849
100 µg/kg/week (n=11)	**5.42** [4.74, 6.11]	0.0218
Pooled Placebo (n=15)	**4.35** [3.75, 4.94]	NA

Additional highlights:

- TransCon CNP demonstrated a consistent dose-dependent increase in AHV across the four dose groups.
- Mean improvements in AHV for TransCon CNP-treated patients were consistent across age groups <5 years and >5 years, with dose response established.
- TransCon CNP at 100 µg/kg/week improved change in ACH-specific height SDS compared to placebo (p=0.0283).
- TransCon CNP was generally well tolerated, with no discontinuations.
- No serious adverse events ("SAEs") related to treatment were reported; two unrelated SAEs were reported.
- Injections were generally well tolerated with low frequency of injection site reactions ("ISRs"):
    - 11 mild ISRs (in 8 patients) out of >2,000 injections.
- Patients treated ≥6 months at 100 µg/kg/week in the blinded or OLE period demonstrated a consistent and sustained response, with mean AHV of 5.39 cm/year (n=40).

One-year data from the OLE portion of the ACcomplisH Trial is expected during the fourth quarter of 2023.

In October 2022, we submitted protocols to initiate ApproaCH, a global randomized, double-blind, placebo-controlled Phase 2b trial of TransCon CNP in children ages 2–11 years with ACH. The trial targets enrollment of ~80 patients. During the second quarter of 2023, we expect to complete enrollment in ApproaCH.

We are also conducting ACHieve, a multi-center natural history study designed to gain insight into the experiences of pediatric subjects with ACH. ACHieve will study growth velocity, body proportionality, and comorbidities over time in children with ACH up to eight years old. No study medication will be administered.

In addition, we are planning a trial to evaluate TransCon CNP in children under the age of 2 years. We plan to submit an IND or similar application for this trial in the third quarter of 2023.

TransCon Product Candidates—Oncology

TransCon for Immuno-Oncology

We believe prolonging therapeutic activity and targeting drug activity to relevant cell types and tissues have the potential to improve treatment outcomes while reducing toxicities, and could offer potential new combination and multi-agent regimens that would not otherwise be feasible. In addition, we believe our TransCon technology platform is well-suited to improve cancer treatments given the large number of validated targets with known limitations. We are currently investigating two clinical-stage product candidates designed to activate the patient's own immune system to eradicate malignant cells.

Clinical Development in Immuno-Oncology

Our two product candidates in Oncology are designed to provide sustained therapeutic levels of an active drug locally (TransCon TLR7/8 Agonist), or systemically (TransCon IL-2 ß/g), which we believe could provide potent and durable systemic anti-tumor efficacy.

TransCon TLR7/8 Agonist for Sustained Localized Release

TransCon TLR7/8 Agonist is an investigational long-acting prodrug, designed for sustained release of resiquimod, a small molecule agonist of TLR 7 and 8. It is designed to provide sustained and potent activation of the innate immune system in the tumor and tumor draining lymph node for weeks following a single intratumoral injection and to have a low risk of systemic toxicity. The transcendIT-101 Trial, a Phase 1/2 clinical trial to evaluate the safety and efficacy of TransCon TLR7/8 Agonist in locally advanced or metastatic solid tumors, alone or in combination with pembrolizumab, is enrolling patients in four indication-specific cohorts.

In November 2022, we announced new data from the dose-escalation portion of transcendIT-101. All 23 of the patients enrolled in the dose escalation portion of the trial had advanced or metastatic solid tumors that had progressed on prior treatments, 9 in the monotherapy cohort (intratumoral TransCon TLR7/8 Agonist alone) and 14 in the combination therapy cohort (intratumoral TransCon TLR7/8 Agonist plus the check-point inhibitor pembrolizumab). Two dose levels were evaluated: 0.3 mg/lesion and 0.5 mg/lesion. The recommended Phase 2 dose was declared at 0.5 mg/lesion for up to two lesions, which is being evaluated in four cohorts focused on cancers where increased TLR activity has potential to improve innate and adaptive immune activation and host defense against cancers. The cohorts include head and neck squamous-cell carcinoma; other HPV-associated cancers; melanoma; and cutaneous squamous cell carcinoma.

TransCon IL-2 ß/g for Sustained Systemic Release

TransCon IL-2 b/g is an investigational long-acting prodrug designed to improve cancer immunotherapy through sustained release of an IL-2 variant that selectively activates IL-2Rß/g, with minimal binding to IL-2Rα. The Phase 1/2 IL-Believe Trial evaluating TransCon IL-2 b/g monotherapy or in combination with pembrolizumab in patients with advanced cancer is enrolling patients in dose escalation cohorts.

In April 2023, we announced that initial dose escalation data from our ongoing Phase 1/2 IL-Believe Trial of TransCon IL-2 β/γ alone or in combination with pembrolizumab has been accepted for online publication at ASCO 2023, the American Society of Clinical Oncology annual meeting held in June. Results from monotherapy dose escalation including data supporting declaration of recommended Phase 2 dose for monotherapy are now expected to be announced during the second quarter of 2023. Combination therapy dose escalation results are expected during the third quarter of 2023.

Other Development Plans

We believe that a combination TransCon TLR7/8 Agonist and TransCon IL-2 b/g may have the potential to produce greater anti-tumor activity than either candidate alone. We plan to evaluate clinical activity of the combination of TransCon TLR7/8 Agonist and TransCon IL-2 b/g in 2023.

TransCon Product Candidates—Ophthalmology

Market Opportunity in Ophthalmology

According to the Centers for Disease Control and Prevention, more than four million Americans aged 40 years and older are either legally blind or live with low vision. Age-related eye diseases such as age-related macular degeneration ("AMD"), cataract, diabetic retinopathy, and glaucoma are the leading causes of blindness and low vision. Advances in technology have resulted in new treatment options for disorders such as wet AMD, diabetic macular edema, and retinal vein occlusion. Through intravitreal injections, medication is placed directly into a space in the back of the eye called the vitreous cavity.

The use of anti-vascular endothelial growth factor ("anti-VEGF") agents have transformed the treatment of wet AMD. Clinical studies have shown that anti-VEGF treatments are very successful in preventing vision loss resulting from wet AMD and may help regain some lost vision. However, anti-VEGF treatment requires repetitive intravitreal injections, representing a high treatment burden for the patients. Lack of adherence and undertreatment remains a significant issue in real-world outcomes, and extending duration of therapeutic effect and reduce treatment frequency remains a key unmet medical need. Intravitreal treatments represent an established, well-understood, and high-value therapeutic category, characterized by high unmet medical need. We estimate the global market for ophthalmology treatments exceeds $10 billion and is primed for disruption.

Our Solution: TransCon Hydrogel for Ophthalmology

Our TransCon Hydrogel platform has been designed to provide sustained levels of a drug at a localized site and to allow for prolonged, continuous release over months. In vivo data demonstrated that the TransCon Hydrogel platform provided continuous local drug release over at least six months, supporting twice yearly administration. By reducing the frequency of intravitreal injection, we believe the TransCon Hydrogel platform could potentially increase patient adherence and persistence, resulting in better outcomes.

Development of TransCon Ophthalmology Pipeline Candidates

TransCon RBZ (ranibizumab) has been selected as our lead pipeline candidate for Ophthalmology. Lucentis® (ranibizumab) was first approved by the FDA in 2006 for the treatment of wet AMD. It has been studied extensively and demonstrated efficacy following sustained infusion from an implantable osmotic minipump. Thus, we believe ranibizumab represents a clinically validated parent drug that could provide lower development risk compared to new candidate discovery.

In addition to TransCon RBZ, we are evaluating additional Ophthalmology product candidates.

Results of Operations

	Three Months Ended March 31,	
	2023	2022
	(EUR'000)	
Statement of Profit or Loss		
Revenue	33,589	6,828
Cost of sales	4,621	4,246
Gross profit / (loss)	**28,968**	**2,582**
Research and development costs	106,114	83,193
Selling, general and administrative expenses	66,539	47,418
Operating profit / (loss)	**(143,685)**	**(128,029)**
Share of profit / (loss) of associate	(1,227)	(4,873)
Finance income	45,135	13,044
Finance expenses	9,840	5,399
Profit / (loss) before tax	**(109,617)**	**(125,257)**
Income taxes (expenses)	(1,297)	(241)
Net profit / (loss) for the period	**(110,914)**	**(125,498)**

We had a net loss of €110.9 million for the three months ended March 31, 2023, compared to a net loss of €125.5 million for the same period last year. Total equity was €167.2 million as of March 31, 2023, compared to €263.3 million as of December 31, 2022. Further details about our results of operations are described in the following sections.

Revenue

Revenue for the three months ended March 31, 2023 was €33.6 million, representing an increase of €26.8 million compared to the three months ended March 31, 2022. This increase was primarily attributable to the higher commercial sale of products and higher revenue from rendering of services, partly offset by lower sale of clinical supply.

The development in quarterly revenue from sale of commercial products in 2022 and 2023, was:

	Three Months Ended,				
	March 31, 2022	June 30, 2022	September 30, 2022	December 31, 2022	March 31, 2023
			(EUR'000)		
Sale of commercial products	**1,888**	**4,435**	**12,252**	**17,084**	**31,551**

Cost of Sales

Cost of sales for the three months ended March 31, 2023 was €4.6 million, representing an increase of €0.4 million compared to the three months ended March 31, 2022. This increase was primarily attributable to higher costs arising from higher commercial revenue, however partly offset by lower cost of sales for clinical supplies.

Research and Development Costs

The following table specifies external project costs on the development pipeline and other research and development costs.

	Three Months Ended March 31,	
	2023	2022
	(EUR'000)	
External project costs		
TransCon hGH	18,010	19,939
TransCon PTH	12,514	11,686
TransCon CNP	10,945	9,555
TransCon IL-2 ß/γ	10,135	1,446
TransCon TLR7/8	8,492	2,137
Other project costs	3,288	602
Total external project costs	**63,384**	**45,365**
Other research and development costs		
Employee costs	31,926	30,417
Other costs	8,100	4,691
Depreciation	2,704	2,720
Total other research and development costs	**42,730**	**37,828**
Total research and development costs	**106,114**	**83,193**

The development of research and development ("R&D") costs reflects the advancement of our pipeline of endocrinology and oncology, where we have multiple prodrug therapies in development, as well as initial activities within our new therapeutic area of ophthalmology.

R&D costs for the three months ended March 31, 2023 was €106.1 million, representing an increase of €22.9 million compared to the three months ended March 31, 2022. This increase was primarily due to higher development costs for our oncology programs, TransCon IL-2 ß/g and TransCon TLR7/8, reflecting the advancement of these product candidates and higher employee and other costs attributable to organizational growth.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses for the three months ended March 31, 2023 was €66.5 million, representing an increase of €19.1 million compared to the three months ended March 31, 2022. This increase was primarily due to higher external commercial expenses related to SKYTROFA and pre-launch activities for TransCon PTH of €8.6 million, higher employee related expenses of €4.4 million, and an increase in other general and administrative expenses attributable to organizational growth of €5.8 million.

Net Profit / (Loss) of Associate

Net loss of associate for the three months ended March 31, 2023 was €1.2 million, representing a decrease of €3.6 million compared to the three months ended March 31, 2022, and reflects our share of loss in VISEN.

Finance Income and Finance Expenses

Finance income for the three months ended March 31, 2023 was €45.1 million, representing an increase of €32.1 million compared to the three months ended March 31, 2022. This increase was primarily due to a €40.1 million higher remeasurement gain on derivative liabilities and €3.7 million higher interest income, partly offset by €11.7 million lower exchange rate gains compared to the same period last year.

Finance expenses for the three months ended March 31, 2023 was €9.8 million, representing an increase of €4.4 million compared to the three months ended March 31, 2022. This increase was primarily due to €8.2 million higher interest and amortization charges on convertible notes, partly offset by €4.2 million lower transaction costs attributable to the convertible notes financing in March 2022.

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.

While COVID-19 had an impact on how we work and conduct our activities, we have managed to avoid significant disruptions to our clinical and manufacturing operations.

We monitor the risks from the 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 2022 Annual Report on Form 20-F.

Liquidity and Capital Resources

Our liquidity and capital resources comprise cash, cash equivalents and marketable securities (“capital resources”).

As of March 31, 2023, these amounted to €585.7 million, specified as follows:

	Carrying amount	Fair value
	(EUR’000)	
March 31, 2023		
Liquidity and capital resources		
Marketable securities	84,460	83,525
Cash and cash equivalents	501,281	501,281
Total liquidity and capital resources	**585,741**	**584,806**
Classification in consolidated statement of financial position		
Current assets	585,741	584,806
Total liquidity and capital resources	**585,741**	**584,806**

As of March 31, 2023, marketable securities had a weighted average duration of 3.4 months and are classified as current positions (i.e., those maturing within twelve months after the reporting date).

Our expenditures primarily relate to research and development activities and selling, general and administrative activities to support our business, including our continued development of therapeutic areas within endocrinology, oncology and ophthalmology, the commercialization of SKYTROFA and expenses made in anticipation of potential 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 through 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 capital resources as of March 31, 2023, 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.

Historically, we have 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. Including our initial public offering, since February 2015, we have completed public offerings of American Depositary Shares (“ADSs”) with net proceeds of $2,256.6 million (or €1,968.4 million at the time of the offerings).

In March 2022, we issued an aggregate principal amount of $575.0 million of fixed rate 2.25% convertible notes. Refer to Note 10, “Financial Assets and Liabilities” for further information. We used $116.7 million (€105.3 million) of the net proceeds from the offering in March 2022 to repurchase 1,000,000 ADSs representing the Company’s ordinary shares. Total holding of treasury shares is disclosed in Note 9, “Treasury Shares.”

For additional description of our cash requirements, public offerings, expense structure and commitments, refer to “Item 5B. Liquidity and Capital Resources,” set forth in our 2022 Annual Report on Form 20-F.

Our future funding requirements will depend on many factors, including, but not limited to:

- the manufacturing, selling and marketing costs associated with our products and product candidates, if approved, including the cost and timing of building our sales and marketing capabilities;
- the timing, receipt, and amount of sales of, or royalties on, TransCon hGH and any future products;
- the sales price and the availability of adequate third-party coverage and reimbursement for our products and product candidates, if approved;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to collect payments which are due to us from customers and collaboration partners (if any), which in turn is impacted by the financial standing of any such customers and collaboration partners;

- the progress, timing, scope, results and costs of our preclinical studies and clinical trials and manufacturing activities for our 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 and the costs of post-marketing studies that could be required by regulatory authorities, including related to the possibility of a delay in the FDA's final regulatory decision on the TransCon PTH NDA;
- 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 commercialization and co-promotion of our products and product candidates, if approved, and our efforts to develop and commercialize our other existing product candidates, including related to any potential delay in the timing of commercial launch for TransCon PTH in the United States, if approved, caused by the FDA's identification of deficiencies in the NDA for TransCon PTH;
- the market opportunities and patient populations for our products and product candidates, if approved, including with respect to TransCon PTH, and our ability to obtain market acceptance of our products and product candidates, if approved; 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 if we need them or on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, scale back or cease our research and development and commercialization activities, preclinical studies and clinical trials.

The following table summarizes our cash flows for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,		
	2023	2022	Change
		(EUR'000)	
Cash flows from / (used in)			
Operating activities	(147,044)	(130,788)	(16,256)
Investing activities	210,646	38,542	172,104
Financing activities	(702)	397,735	(398,437)
Net increase / (decrease) in cash and cash equivalents	**62,900**	**305,489**	**(242,589)**

Cash Flows from / (used in) Operating Activities

Cash flows used in operating activities for the three months ended March 31, 2023 was €147.0 million, representing an increase of €16.3 million compared to the three months ended March 31, 2022. This increase was primarily attributable to a €21.0 million higher loss for the period when adjusted for non-operating financial income and expenses, taxes and non-cash items.

Cash Flows from / (used in) Investing Activities

Cash flows from investing activities for the three months ended March 31, 2023 was €210.6 million, representing an increase of €172.1 million compared to the three months ended March 31, 2022. This increase was primarily attributable to net settlements of marketable securities of €173.2 million in line with our liquidity management strategy.

Cash Flows from / (used in) Financing Activities

Cash flows used in financing activities for the three months ended March 31, 2023 was €0.7 million, representing a decrease of €398.4 million compared to cash flows from financing activities for the three months ended March 31, 2022. This decrease was primarily attributable to the convertible notes issuance and acquisition of treasury shares completed during the three months ended March 31, 2022.

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 financial risks of changes in foreign currency exchange rates, inflation 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, equity 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 Swiss Franc and the British Pound. We have received payments in U.S. Dollars under our collaboration and license agreements, 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. In addition, our outstanding convertible notes are denominated 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

Outstanding convertible notes comprise a 2.25% coupon fixed rate structure. In addition, the interest rate on lease liabilities is fixed at the lease commencement date. Future indebtedness, including those related to lease arrangements, if any, may be subject to higher interest rates. In addition, future interest income from interest-bearing bank deposits and marketable securities may fall short of expectations due to changes in interest rates.

Derivative liabilities are measured at fair value through profit or loss. Accordingly, since the fair value is exposed from the development in interest rates, the profit or loss is exposed to volatility from such development.

Inflation Risk

Inflation affects us as our vendors may pass on any increased costs to us and accordingly increase our R&D costs, SG&A expenses and cost of manufacturing. We do not believe that inflation had a material impact on our results of operation for the three months ended March 31, 2023.

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-ratings (minimum A2/A-) assigned by international credit-rating agencies.

We maintain the majority of our cash and cash equivalents in accounts with major financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. The banks are reviewed on a regular basis and deposits may be transferred during the year to mitigate credit risk.

In order to mitigate the concentration of credit risks on bank deposits and to preserve capital, a portion of the bank deposits have been placed into primarily U.S. treasury bills, U.S. government bonds and corporate bonds. Our investment policy, approved by the Board, only allows investment in marketable securities having investment grade credit-ratings, assigned by international credit-rating agencies. Accordingly, the risk from probability of default is low.

On each reporting date, we consider the risk of expected credit loss on bank deposits and marketable securities, including the hypothetical impact arising from the probability of default, which is considered in conjunction with the expected loss caused by default by banks or securities with similar credit-ratings and attributes. In line with previous periods, this assessment did not reveal a material impairment loss, and accordingly no provision for expected credit loss has been recognized.

Equity Risk

We are exposed from the development in the Company’s share price, when remeasuring derivative liabilities at fair value.

Derivative liabilities relate to the foreign currency conversion option embedded in the convertible notes and are measured at fair value through profit or loss. Fair value cannot be measured based on quoted prices in active markets, or other observable input, and accordingly, derivative liabilities are measured by using the Black-Scholes option pricing model, where the pricing is exposed from changes in the Company’s share price. Sensitivity analysis over derivative liabilities is disclosed in Note 10, “Financial Assets and Liabilities.”