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 September, 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 June 30, 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: September 5, 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 and Six Months Ended June 30, 2023 and 2022

	Notes	Three Months Ended June 30,		Six Months Ended June 30,	
		2023	2022	2023	2022
		(EUR'000)		(EUR'000)	
Consolidated Statement of Profit or Loss					
Revenue	**5**	47,393	6,160	80,982	12,988
Cost of sales		12,929	1,086	17,551	5,332
Gross profit		**34,464**	**5,074**	**63,431**	**7,656**
Research and development costs		105,021	90,383	211,134	173,576
Selling, general and administrative expenses		70,281	56,584	136,820	104,002
Operating profit / (loss)		**(140,838)**	**(141,893)**	**(284,523)**	**(269,922)**
Share of profit / (loss) of associate		(7,451)	(1,166)	(8,677)	(6,039)
Finance income		35,761	71,127	80,374	84,171
Finance expenses		9,334	9,434	18,652	14,833
Profit / (loss) before tax		**(121,862)**	**(81,366)**	**(231,478)**	**(206,623)**
Income taxes (expenses)		429	47	(868)	(195)
Net profit / (loss) for the period		**(121,433)**	**(81,319)**	**(232,346)**	**(206,818)**
Attributable to owners of the Company		(121,433)	(81,319)	(232,346)	(206,818)
Basic and diluted earnings / (loss) per share		€ (2.16)	€ (1.46)	€ (4.14)	€ (3.68)
Number of shares used for calculation (basic and diluted) [1]		56,218,257	55,805,486	56,155,441	56,260,248

	(EUR'000)		(EUR'000)	
Statement of Comprehensive Income				
Net profit / (loss) for the period	**(121,433)**	**(81,319)**	**(232,346)**	**(206,818)**
Other comprehensive income / (loss)				
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translating foreign operations	(1,016)	(757)	(1,803)	(332)
Other comprehensive income / (loss) for the period, net of tax	**(1,016)**	**(757)**	**(1,803)**	**(332)**
Total comprehensive income / (loss) for the period, net of tax	**(122,449)**	**(82,076)**	**(234,149)**	**(207,150)**
Attributable to owners of the Company	(122,449)	(82,076)	(234,149)	(207,150)

[1] As of June 30, 2023 and June 30, 2022, a total of 6,866,241 and 7,033,103 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	June 30, 2023	December 31, 2022
		(EUR'000)	
Assets			
Non-current assets			
Intangible assets		4,606	4,828
Property, plant and equipment		125,362	129,095
Investment in associate		14,111	22,932
Other receivables	**10**	2,066	1,920
Marketable securities	**10**	—	7,492
		146,145	**166,267**
Current assets			
Inventories		167,919	130,673
Trade receivables	**10**	20,212	11,910
Income tax receivables		1,360	883
Other receivables	**10**	14,127	12,833
Prepayments		42,958	31,717
Marketable securities	**10**	36,880	290,688
Cash and cash equivalents	**10**	394,222	444,767
		677,678	**923,471**
Total assets		**823,823**	**1,089,738**
Equity and liabilities			
Equity			
Share capital	**8**	7,699	7,675
Distributable equity		57,142	255,673
Total equity		**64,841**	**263,348**
Non-current liabilities			
Borrowings	**10**	479,374	482,956
Derivative liabilities	**10**	86,385	157,950
Contract liabilities		949	14,213
		566,708	**655,119**
Current liabilities			
Borrowings	**10**	26,564	25,421
Contract liabilities		4,146	—
Trade payables and accrued expenses	**10**	122,120	101,032
Other liabilities		22,860	31,989
Income tax payables		5,773	5,490
Provisions		10,811	7,339
		192,274	**171,271**
Total liabilities		**758,982**	**826,390**
Total equity and liabilities		**823,823**	**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	—	—	—	—	(232,346)	**(232,346)**
Other comprehensive income / (loss), net of tax	—	—	—	(1,803)	—	**(1,803)**
Total comprehensive income / (loss)	**—**	**—**	**—**	**(1,803)**	**(232,346)**	**(234,149)**
Transactions with Owners						
Share-based payment (Note 7)	—	—	—	—	33,568	**33,568**
Capital increase	24	2,050	—	—	—	**2,074**
Equity at June 30, 2023	**7,699**	**2,114,913**	**(149)**	**1,649**	**(2,059,271)**	**64,841**

		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	—	—	—	—	(206,818)	**(206,818)**
Other comprehensive income / (loss), net of tax	—	—	—	(332)	—	**(332)**
Total comprehensive income / (loss)	**—**	**—**	**—**	**(332)**	**(206,818)**	**(207,150)**
Transactions with Owners						
Share-based payment (Note 7)	—	—	—	—	36,770	**36,770**
Acquisition of treasury shares (Note 9)	—	—	(134)	—	(105,965)	**(106,099)**
Capital increase	3	683	—	—	—	**686**
Equity at June 30, 2022	**7,649**	**2,108,422**	**(155)**	**3,447**	**(1,511,521)**	**607,842**

Unaudited Condensed Consolidated Interim Cash Flow Statements for the Six Months Ended June 30, 2023 and 2022

	Six Months Ended June 30,	
	2023	2022
	(EUR'000)	
Operating activities		
Net profit / (loss) for the period	**(232,346)**	**(206,818)**
Reversal of finance income	(80,374)	(84,171)
Reversal of finance expenses	18,652	14,833
Reversal of gain and loss on disposal of property, plant and equipment	21	14
Reversal of income taxes (expenses)	868	195
Increase / (decrease) in provisions	3,625	3,529
Adjustments for non-cash items:		
Non-cash consideration relating to revenue	(1,203)	(1,275)
Share of profit / (loss) of associate	8,677	6,039
Share-based payment	33,568	36,770
Depreciation	8,969	8,584
Amortization	222	222
Changes in working capital:		
Inventories	(37,246)	(25,917)
Receivables	(10,715)	(5,698)
Prepayments	(12,779)	(9,637)
Contract liabilities (deferred income)	(9,118)	(1,865)
Trade payables, accrued expenses and other payables	9,316	7,960
Cash flows generated from / (used in) operations	**(299,863)**	**(257,235)**
Finance income received	8,403	3,828
Finance expenses paid	(7,746)	(1,242)
Income taxes received / (paid)	(966)	(532)
Cash flows from / (used in) operating activities	**(300,172)**	**(255,181)**
Investing activities		
Acquisition of property, plant and equipment	(1,529)	(7,544)
Reimbursement from acquisition of property, plant and equipment	—	9,535
Purchase of marketable securities	—	(89,700)
Settlement of marketable securities	259,132	136,139
Cash flows from / (used in) investing activities	**257,603**	**48,430**
Financing activities		
Payment of principal portion of lease liabilities	(5,085)	(3,163)
Net proceeds from convertible senior notes	—	503,281
Proceeds from exercise of warrants	2,074	686
Acquisition of treasury shares, net of transaction costs	—	(105,304)
Cash flows from / (used in) financing activities	**(3,011)**	**395,500**
Increase / (decrease) in cash and cash equivalents	**(45,580)**	**188,749**
Cash and cash equivalents at January 1	444,767	446,267
Effect of exchange rate changes on balances held in foreign currencies	(4,965)	37,371
Cash and cash equivalents at June 30	**394,222**	**672,387**
Cash and cash equivalents include:		
Bank deposits	394,222	670,244
Short-term marketable securities	—	2,143
Cash and cash equivalents at June 30	**394,222**	**672,387**

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 September 5, 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 June 30, 2023, to be presented as current liabilities.

On June 30, 2023, the carrying amount of convertible notes and derivative liabilities were €402.7 million and €86.4 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 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 the Company's 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.

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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(EUR'000)		(EUR'000)	
Revenue from external customers				
Commercial sale of products	35,895	4,435	67,446	6,323
Rendering of services	10,909	612	12,079	983
Sale of clinical supply	—	470	254	4,407
Licenses	589	643	1,203	1,275
Total revenue from external customers	**47,393**	**6,160**	**80,982**	**12,988**
Attributable to				
Commercial customers	35,895	4,435	67,446	6,323
Collaboration partners and license agreements	11,498	1,725	13,536	6,665
Total revenue from external customers	**47,393**	**6,160**	**80,982**	**12,988**
Specified by timing of recognition				
Recognized over time	10,909	612	12,079	983
Recognized at a point in time	36,484	5,548	68,903	12,005
Total revenue from external customers	**47,393**	**6,160**	**80,982**	**12,988**
Revenue by geographical location				
Europe	—	140	—	275
North America	46,758	5,078	79,828	11,535
China	635	942	1,154	1,178
Total revenue from external customers	**47,393**	**6,160**	**80,982**	**12,988**

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 and six months ended June 30, 2023 and 2022, share-based compensation costs recognized in the unaudited condensed consolidated interim statement of profit or loss were €19.9 million and €33.6 million, respectively, and €16.8 million and €36.8 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 targets as determined by the Board, provided that no more than 10% of each tranche may be directly attributable to accomplishment of financial results achieved in the financial year prior to the vesting date. Exceeding performance targets 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 June 30, 2023:

	Restricted Stock Units	Performance Stock Units	Total
Outstanding		(Number)	
January 1, 2023	82,492	—	82,492
Granted during the period	609,860	112,268	722,128
Forfeited during the period	(29,483)	—	(29,483)
June 30, 2023	**662,869**	**112,268**	**775,137**
Specified by vesting year			
2023	40,794	—	40,794
2024	234,469	37,422	271,891
2025	193,779	37,423	231,202
2026	193,827	37,423	231,250
June 30, 2023	**662,869**	**112,268**	**775,137**

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 six months ended June 30, 2023:

	Total Warrants	Weighted Average Exercise Price
	(Number)	(EUR)
Outstanding		
January 1, 2023	6,864,011	81.30
Granted during the period	274,045	91.25
Exercised during the period	(183,201)	11.09
Forfeited during the period	(88,614)	113.91
June 30, 2023	**6,866,241**	**83.16**
Vested at June 30, 2023	**5,227,588**	**72.56**

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 57,335,496 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%
June 30, 2023	**149**	**1,113,152**	**1.9%**

Note 10—Financial Assets and Liabilities

Financial assets comprise marketable securities, cash and cash equivalents, and receivables. Financial liabilities comprise convertible notes and lease liabilities, presented as borrowings on the statement of financial position, derivative liabilities, and trade payables and accrued expenses.

Marketable Securities

The following table specifies the marketable securities portfolio:

	June 30, 2023	December 31, 2022
	(EUR'000)	
Marketable securities		
U.S. Treasury bills	—	79,086
U.S. Government bonds	21,576	99,337
Corporate bonds	15,304	104,236
Agency bonds	—	15,521
Total marketable securities	**36,880**	**298,180**
Classified based on maturity profiles		
Non-current assets	—	7,492
Current assets	36,880	290,688
Total marketable securities	**36,880**	**298,180**
Specified by rate structure		
Fixed rate	35,760	205,825
Floating rate	1,120	11,787
Zero-coupon	—	80,568
Total marketable securities	**36,880**	**298,180**
Specified by investment grade credit rating		
High grade	21,576	203,530
Upper medium grade	15,304	94,650
Total marketable securities	**36,880**	**298,180**

The portfolio of marketable securities is all denominated in U.S. Dollars. At June 30, 2023 and December 31, 2022, the portfolio had a weighted average duration of 3.1 months and 3.2 months, respectively. 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 June 30, 2023, the carrying amount of the convertible notes was €402.7 million, and the fair value was approximately €381.2 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 (51% as of June 30, 2023).

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

Sensitivity Analysis

On June 30, 2023, all other inputs and assumptions held constant, a 10% relative increase in volatility, will increase the fair value of derivative liabilities by approximately €12.3 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 June 30, 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 €16.7 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 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 is quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date;

Level 2 is based on valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable;

Level 3 is based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

	June 30, 2023		December 31, 2022		
	Carrying amount	Fair value	Carrying amount	Fair value	Fair value level
	(EUR'000)				(1-3)
Financial assets					
Marketable securities	36,880	36,461	298,180	295,843	1
Financial assets measured at amortized cost	**36,880**	**36,461**	**298,180**	**295,843**	
Total financial assets	**36,880**	**36,461**	**298,180**	**295,843**	
Financial liabilities					
Convertible senior notes	402,686	381,161	399,186	382,459	3
Financial liabilities measured at amortized cost	**402,686**	**381,161**	**399,186**	**382,459**	
Derivative liabilities	86,385	86,385	157,950	157,950	3
Financial liabilities measured at fair value through profit or loss	**86,385**	**86,385**	**157,950**	**157,950**	
Total financial liabilities	**489,071**	**467,546**	**557,136**	**540,409**	

The following table specifies movements in level 3 fair value measurements:

	2023	2022
	(EUR'000)	
Derivative liabilities		
January 1	157,950	—
Additions	—	142,467
Remeasurement recognized in financial (income) or expense	(71,565)	(40,436)
June 30	**86,385**	**102,031**

Maturity Analysis

The following table summarizes maturity analysis (on an undiscounted basis) for non-derivative financial liabilities recognized in the unaudited condensed consolidated statements of financial position at June 30, 2023:

	< 1 year	1-5 years	>5 years	Total contractual cash-flows	Carrying amount
			(EUR'000)		
Financial liabilities					
June 30, 2023					
Borrowings					
Convertible senior notes	11,906	576,799	—	588,705	402,686
Lease liabilities	14,054	52,174	54,625	120,853	103,252
Trade payables and accrued expenses	122,120	—	—	122,120	122,120
Total financial liabilities	**148,080**	**628,973**	**54,625**	**831,678**	**628,058**

Note 11—Subsequent Events

On September 5, 2023, the Company entered into a $150 million capped synthetic royalty funding agreement (the “Royalty Pharma Agreement”) with Royalty Pharma (the “Purchaser”). Under the terms of the Royalty Pharma Agreement, the Company receives an upfront payment of $150 million (the “Purchase Price”) in exchange for a 9.15% royalty on net U.S. SKYTROFA revenue, beginning on January 1, 2025. The royalty payments to the Purchaser will cease upon reaching a multiple of the Purchase Price of 1.925x, or 1.65x if the Purchaser receives royalties in that amount by December 31, 2031. The Royalty Pharma Agreement includes certain buy-out options under various terms and conditions.

No other events have occurred after the balance sheet 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 resubmission of the TransCon PTH New Drug Application ("NDA") and timing of the U.S. Food & Drug Administration's ("FDA") final regulatory decision;
- 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;
- our expectations regarding the launch of SKYTROFA in Germany;
- 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, timing, 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 our new TransCon technology carrier platform;
- 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 biopharma 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; and
- the impact of international economic, political, legal, compliance, social and business factors, including inflation.

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 Disease, 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

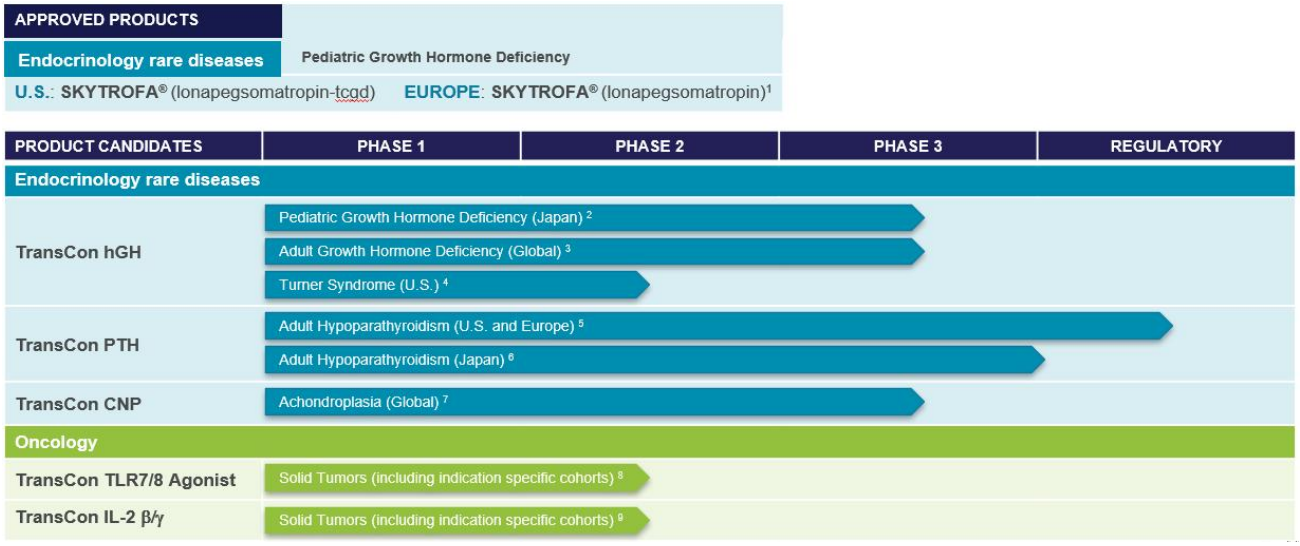
When we apply our TransCon technology platform to clinically validated parent drugs or pathways, we may benefit from established clinical safety and efficacy data, which we believe increases the probability of success compared to traditional drug development. As presented in the graphic below, our algorithm 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 Disease 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"). TransCon hGH is a prodrug of somatropin ("hGH"), administered once weekly, composed of an unmodified somatropin 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 daily hGH therapy that is the current standard of care. SKYTROFA is 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 in new markets, adult GHD, and Turner Syndrome; TransCon PTH, an investigational prodrug of parathyroid hormone composed of PTH(1-34), designed to be administered once-daily for adult patients with hypoparathyroidism; and TransCon CNP, an investigational prodrug of C-type natriuretic peptide ("CNP") designed to be administered once-weekly, for children with 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, an investigational long-acting prodrug designed for sustained release of an IL-2 variant that selectively activates IL-2Rß/g, for systemic delivery. 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. *Re-submission of NDA to the FDA pending – 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, EC decision anticipated Q4 2023*
6. *PaTHway Japan Trial*
7. *ApproaCH Trial*
8. *transcendIT-101 Trial, including 4 indication-specific cohorts*
9. *IL-Believe Trial*

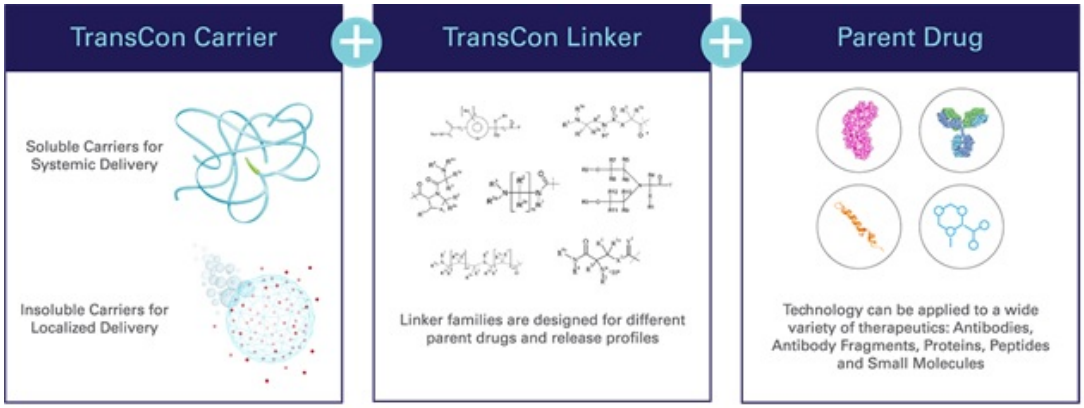
Global Commercialization Strategy

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.



We recently announced a new TransCon technology carrier platform with the potential to unlock large market opportunities, where high volume and low-cost manufacturing is required, and demonstrated proof-of-principle for GLP-1 analogs (semaglutide), with data supporting potential best-in-class weekly and monthly administration profiles.

TransCon Products – Endocrinology Rare Disease

TransCon Growth Hormone (hGH) for Pediatric Growth Hormone Deficiency

TransCon hGH is a prodrug of somatropin 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 daily hGH therapy.

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.

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 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.

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. 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 pediatric 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 administered once-daily to achieve and maintain a steady concentration of PTH in the bloodstream, thereby more fully addressing all aspects of the disease including normalizing serum and urinary calcium and serum phosphate levels and reducing the burden of conventional therapy. 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 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.

Following receipt of our Day 180 assessment report of our Marketing Authorisation Application (“MAA”) which was submitted to the EMA in November 2022, we remain on track for an EC decision on the MAA for TransCon PTH during the fourth quarter of 2023. If approved, the first launch is planned in Germany in early 2024.

In June 2023, we requested a Type A meeting with FDA and submitted an updated control strategy. The Type A meeting was held with FDA in late August based on the Agency’s availability. Following a constructive Type A meeting, we submitted additional information to FDA supporting the updated control strategy. We believe the materials submitted to FDA combined with the Type A meeting discussions will position us to resubmit the NDA for TransCon PTH for adults with hypoparathyroidism in October 2023.

On June 17, 2023, we announced one-year (Week 52) data from the open-label extension (“OLE”) portion of the Phase 3 PaTHway Trial of TransCon PTH in adults with hypoparathyroidism. PaTHway is a Phase 3 trial of TransCon PTH with a placebo ("PBO")-controlled 26-week blinded portion and a 156-week OLE portion, designed to evaluate the long-term efficacy and safety of TransCon PTH as a potential hormone therapy for adult patients diagnosed with hypoparathyroidism. Of the 82 study participants dosed, 79 completed blinded treatment and entered the OLE, and 78 (59 TransCon PTH/TransCon PTH, 19 PBO/TransCon PTH) completed Week 52. The data showed that treatment with TransCon PTH resulted in sustained improvements through Week 52, as well as safety and tolerability similar to that reported for the initial 26-week blinded portion of the trial.

Week 52 Highlights

- 95% of patients in the OLE (74 out of 78) achieved independence from conventional therapy (defined as no active vitamin D and calcium supplements of <600mg/day), and none required active vitamin D.
- At Week 52, 81% of participants treated with TransCon PTH achieved both normal serum calcium and independence from conventional therapy.

- TransCon PTH continued to be well-tolerated in the Phase 3 open-label extension, with no new safety signal identified. Most treatment emergent adverse events were mild or moderate (Grades 1-2) and none reported during the OLE through Week 52 led to discontinuation of the study drug or trial.

As of June 30, 2023, 76 out of 79 patients have exceeded two years of follow-up in the PaTHway Trial.

On June 5, 2023, we announced that we started enrollment for a Compassionate Use Program ("CUP") in Germany for TransCon PTH (palopegteriparatide). The CUP was approved by Germany's Federal Institute for Drugs & Medical Devices (Bundesinstitut für Arzneimittel & Medizinprodukte). Through the CUP, treating physicians can request TransCon PTH (palopegteriparatide) for eligible adult patients with hypoparathyroidism whose clinical condition, in the opinion of the treating physician, requires PTH treatment with palopegteriparatide, and who cannot be adequately treated with currently approved products or participate in a palopegteriparatide clinical trial.

On May 1, 2023, we announced that the FDA issued a complete response letter for the TransCon PTH (palopegteriparatide) NDA for the treatment of adults with hypoparathyroidism. In the letter, the FDA cited concerns related to the manufacturing control strategy for variability of delivered dose in the TransCon PTH drug/device combination product. The FDA did not express concern about the clinical data submitted as part of the NDA package and no new preclinical studies, or Phase 3 clinical trials to evaluate safety or efficacy, were requested in the letter.

On January 8, 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. As of June 30, 2023, 12 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, allowing U.S. physicians to request access to investigational TransCon PTH for their eligible patients.

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 June 30, 2023, 57 out of the 59 patients continued in the OLE portion of the trial, where they receive an individualized 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.

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

Our ongoing pivotal, Phase 3 ApproaCH Trial and Phase 2 ACcomplisH trial, as well as our long-term extension trial AttaCH, are evaluating the safety and efficacy TransCon CNP in children with ACH.

On September 5, 2023, we announced completion of enrollment in ApproaCH with a total of 84 subjects randomized. U.S. and EU regulatory agencies have endorsed ApproaCH, a global randomized, double-blind, placebo-controlled trial in children ages 2–11 years with achondroplasia, as a pivotal Phase 3 trial. The primary endpoint of the trial is annualized growth velocity at 52 weeks with additional endpoints analyzing achondroplasia-related co-morbidities and quality of life. Topline results from the ApproaCH trial are expected in the second half of 2024.

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, 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 was superior to placebo on 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 June 30, 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 follow-up from the OLE portion of the ACcomplisH Trial is expected during the fourth quarter of 2023.

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. We also plan to submit an IND or similar application in the fourth quarter of 2023 for the evaluation of TransCon CNP in combination with TransCon hGH.

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.

On May 31, 2023, we announced additional follow-up from the Phase1/2 transcendIT-101 Trial indicating further clinical activity in patients receiving TransCon TLR7/8 Agonist as monotherapy or in combination with pembrolizumab. Enrollment continues in the Phase 2 portion of transcendIT-101 at the recommended Phase 2 dose ("RP2D") of 0.5 mg/lesion for up to two lesions, which is being evaluated in four indication-specific cohorts focused on cancers where increased TLR activity has potential to improve innate and adaptive immune activation and host defense against cancers.

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 RP2D was declared at 0.5 mg/lesion for up to two lesions, which is being evaluated in four cohorts focused on cancers.

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.

On September 5, 2023, we announced completion of the Phase 1 dose escalation in combination with pembrolizumab of the Phase 1/2 IL-Believe Trial with RP2D determined at 120 µg/kg IV every three weeks. Twenty-one patients were enrolled. No dose limiting toxicity, vascular leak syndrome, or grade 3 or 4 cytokine release syndrome was observed at any dose level evaluated.

On May 31, 2023, we announced completion of the Phase 1 monotherapy dose escalation of the Phase 1/2 IL-Believe Trial with RP2D determined at 120 µg/kg IV every three weeks. Twenty-five heavily pre-treated patients were enrolled (median of four prior lines of systemic therapies). Eight monotherapy patients dosed at RP2D; of the three efficacy evaluable patients to date, one partial response in a metastatic colorectal cancer patient, and one stable disease in a renal cell carcinoma patient (data cut April 28, 2023). At RP2D, TransCon IL-2 β/γ was generally well-tolerated with no dose limiting toxicity observed, no vascular leak syndrome and no grade 3 or 4 cytokine release syndrome.

Topline/interim analysis from Phase 2 dose expansion cohorts are expected in 2024.

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.

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

Comparison of the Three and Six Months Ended June 30, 2023 and 2022 (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(EUR'000)		(EUR'000)	
Statement of Profit or Loss				
Revenue	47,393	6,160	80,982	12,988
Cost of sales	12,929	1,086	17,551	5,332
Gross profit / (loss)	**34,464**	**5,074**	**63,431**	**7,656**
Research and development costs	105,021	90,383	211,134	173,576
Selling, general and administrative expenses	70,281	56,584	136,820	104,002
Operating profit / (loss)	**(140,838)**	**(141,893)**	**(284,523)**	**(269,922)**
Share of profit / (loss) of associate	(7,451)	(1,166)	(8,677)	(6,039)
Finance income	35,761	71,127	80,374	84,171
Finance expenses	9,334	9,434	18,652	14,833
Profit / (loss) before tax	**(121,862)**	**(81,366)**	**(231,478)**	**(206,623)**
Income taxes (expenses)	429	47	(868)	(195)
Net profit / (loss) for the period	**(121,433)**	**(81,319)**	**(232,346)**	**(206,818)**

We had a net loss of €232.3 million for the six months ended June 30, 2023, compared to a net loss of €206.8 million for the same period last year. Total equity was €64.8 million as of June 30, 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 and six months ended June 30, 2023 was €47.4 million and €81.0 million, representing an increase of €41.2 million and €68.0 million, respectively, compared to the three and six months ended June 30, 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. For the three months ended June 30, 2023, sale of commercial products was negatively impacted by an adjustment to provision for estimated sales rebates related to sales from prior periods of €2.1 million.

The development in quarterly revenue from sale of commercial products from the second quarter of 2022 to the second quarter of 2023 was:

	Three Months Ended,				
	June 30, 2022	September 30, 2022	December 31, 2022	March 31, 2023	June 30, 2023
			(EUR'000)		
Sale of commercial products	**4,435**	**12,252**	**17,084**	**31,551**	**35,895**

Cost of Sales

Cost of sales for the three and six months ended June 30, 2023 was €12.9 million and €17.6 million, representing an increase of €11.8 million and €12.2 million, respectively, compared to the three and six months ended June 30, 2022. This increase was primarily attributable to higher non-commercial activities as well as higher commercial revenue.

Research and Development Costs

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(EUR'000)		(EUR'000)	
External project costs				
TransCon hGH	12,882	22,927	30,888	42,867
TransCon PTH	10,100	10,892	22,614	22,578
TransCon CNP	13,473	7,558	24,418	17,113
TransCon IL-2 ß/γ	7,745	1,909	17,881	3,355
TransCon TLR7/8	12,081	5,511	20,574	7,648
Other project costs	3,861	1,684	7,150	2,285
Total external project costs	**60,142**	**50,481**	**123,525**	**95,846**
Other research and development costs				
Employee costs	35,411	31,353	67,336	61,771
Other costs	6,349	5,844	14,450	10,534
Depreciation	3,119	2,705	5,823	5,425
Total other research and development costs	**44,879**	**39,902**	**87,609**	**77,730**
Total research and development costs	**105,021**	**90,383**	**211,134**	**173,576**

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

R&D costs for the three and six months ended June 30, 2023 was €105.0 million and €211.1 million, representing an increase of €14.6 million and €37.6 million, respectively, compared to the three and six months ended June 30, 2022. This increase was primarily due to higher development costs for our oncology programs TransCon IL-2 ß/g and TransCon TLR7/8, reflecting increasing product development and clinical trial activities for these product candidates, increasing clinical trial activities for TransCon CNP, and higher employee and other costs attributable to organizational growth, partly offset by lower development costs for TransCon hGH.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses for the three and six months ended June 30, 2023 was €70.3 million and €136.8 million, representing an increase of €13.7 million and €32.8 million, respectively, compared to the three and six months ended June 30, 2022. This increase was primarily due to higher external commercial expenses related to SKYTROFA in the U.S., pre-launch activities for SKYTROFA outside the U.S., global pre-launch activities for TransCon PTH, higher employee related expenses and other general and administrative expenses attributable to organizational growth.

Finance Income and Finance Expenses

Finance income for the three and six months ended June 30, 2023 was €35.8 million and €80.4 million, representing a decrease of €35.4 million and €3.8 million, respectively, compared to the three and six months ended June 30, 2022. For the three months ended June 30, 2023, the decrease was primarily due to €29.5 million lower exchange rate gains and €9.0 million lower gain on derivative liabilities, partly offset by €3.1 million higher interest income compared to the same period last year. For the six months ended June 30, 2023, the decrease was primarily due to €41.7 million lower exchange rate gains, partly offset by €31.1 million higher gain on derivative liabilities and €6.7 million higher interest income compared to the same period last year.

Finance expenses for the three and six months ended June 30, 2023 was €9.3 million and €18.7 million, representing a decrease of €0.1 million and an increase of €3.8 million, respectively, compared to the three and six months ended June 30, 2022. For the three months ended June 30, 2023, the expenses were in line with the same period last year, and for the six months ended June 30, 2023, the increase of €3.8 million was primarily due to €8.6 million higher amortization charges and interest on convertible notes, partly offset by €4.2 million lower transaction costs attributable to the convertible notes compared to the same period last year.

Liquidity and Capital Resources

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

As of June 30, 2023, these amounted to €431.1 million, specified as follows:

	Carrying amount	Fair value
	(EUR'000)	
June 30, 2023		
Liquidity and capital resources		
Marketable securities	36,880	36,461
Cash and cash equivalents	394,222	394,222
Total liquidity and capital resources	**431,102**	**430,683**

As of June 30, 2023, marketable securities had a weighted average duration of 3.1 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 June 30, 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 our ordinary shares. The holding of treasury shares is disclosed in Note 9, "Treasury Shares."

On September 5, 2023, we entered into a $150 million capped synthetic royalty funding agreement (the "Royalty Pharma Agreement") with Royalty Pharma (the "Purchaser"). Under the terms of the Royalty Pharma Agreement, in exchange for the Purchaser's payment of a cash purchase price of $150 million at closing (the "Purchase Price"), we have agreed to sell to the Purchaser its right to receive payment in full of 9.15% on net U.S. SKYTROFA revenue, beginning on January 1, 2025. The royalty payments to the Purchaser will cease upon reaching a multiple of the Purchase Price of 1.925x, or 1.65x if the Purchaser receives royalties in that amount by December 31, 2031. The Royalty Pharma Agreement includes certain buy-out options under various terms and conditions.

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 six months ended June 30, 2023 and 2022:

	Six Months Ended June 30,		
	2023	2022	Change
		(EUR'000)	
Cash flows from / (used in)			
Operating activities	(300,172)	(255,181)	(44,991)
Investing activities	257,603	48,430	209,173
Financing activities	(3,011)	395,500	(398,511)
Net increase / (decrease) in cash and cash equivalents	**(45,580)**	**188,749**	**(234,329)**

Cash Flows from / (used in) Operating Activities

Cash flows used in operating activities for the six months ended June 30, 2023 was €300.2 million, representing an increase of €45.0 million compared to the six months ended June 30, 2022. This increase was primarily attributable to a €17.2 million higher loss for the period when adjusted for non-operating financial income and expenses, taxes and non-cash items. In addition, the increase relates to higher working capital balances of €25.4 million, primarily higher inventories and receivables due to increased commercial activities, and lower contract liabilities due to deferred income, which was recognized as revenue in the period.

Cash Flows from / (used in) Investing Activities

Cash flows from investing activities for the six months ended June 30, 2023 was €257.6 million, representing an increase of €209.2 million compared to the six months ended June 30, 2022. This increase was primarily attributable to €212.6 million higher net settlements of marketable securities in line with our liquidity management strategy.

Cash Flows from / (used in) Financing Activities

Cash flows used in financing activities for the six months ended June 30, 2023 was €3.0 million, representing a decrease of €398.5 million compared to cash flows from financing activities for the six months ended June 30, 2022. This decrease was primarily attributable to the convertible notes issuance and acquisition of treasury shares completed during the six months ended June 30, 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 and six months ended June 30, 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 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. The marketable securities portfolio is disclosed in Note 10, “Financial Assets and Liabilities.”

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 our 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 our share price. Sensitivity analysis over derivative liabilities is disclosed in Note 10, “Financial Assets and Liabilities.”