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

FORM 6-K

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

For the month of November, 2022

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, and 333-261550) 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 September 30, 2022, 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: November 2, 2022

By: /s/ Michael Wolff Jensen
Michael Wolff Jensen
Senior 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 Nine Months Ended September 30, 2022 and 2021

	Notes	Three Months Ended September 30,		Nine Months Ended September 30,	
		2022	2021	2022	2021
		(EUR'000)		(EUR'000)	
Statement of Profit or Loss					
Revenue	**5**	15,290	1,113	28,278	2,881
Cost of sales		1,693	—	7,025	—
Gross profit		**13,597**	**1,113**	**21,253**	**2,881**
Research and development costs		97,431	58,761	271,006	230,216
Selling, general and administrative expenses		60,671	39,284	164,675	111,876
Operating profit / (loss)		**(144,505)**	**(96,932)**	**(414,428)**	**(339,211)**
Share of profit / (loss) of associate		(3,696)	(3,855)	(9,736)	19,434
Finance income		20,326	21,321	73,797	44,589
Finance expenses		41,247	877	25,381	2,580
Profit / (loss) before tax		**(169,122)**	**(80,343)**	**(375,748)**	**(277,768)**
Tax on profit / (loss) for the period		167	(5)	(28)	253
Net profit / (loss) for the period		**(168,955)**	**(80,348)**	**(375,776)**	**(277,515)**
Attributable to owners of the Company		(168,955)	(80,348)	(375,776)	(277,515)
Basic and diluted earnings / (loss) per share		€ (3.03)	€ (1.47)	€ (6.70)	€ (5.13)
Number of shares used for calculation (basic and diluted) [(1)]		55,831,561	54,639,597	56,115,782	54,085,793

		(EUR'000)		(EUR'000)	
Statement of Comprehensive Income					
Net profit / (loss) for the period		**(168,955)**	**(80,348)**	**(375,776)**	**(277,515)**
Other comprehensive income / (loss)					
Items that may be reclassified subsequently to profit or loss:					
Exchange differences on translating foreign operations		(2,207)	1,016	(2,538)	2,781
Other comprehensive income / (loss) for the period, net of tax		**(2,207)**	**1,016**	**(2,538)**	**2,781**
Total comprehensive income / (loss) for the period, net of tax		**(171,162)**	**(79,332)**	**(378,314)**	**(274,734)**
Attributable to owners of the Company		(171,162)	(79,332)	(378,314)	(274,734)

(1) As of September 30, 2022, a total of 6,937,495 warrants outstanding, 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. Similarly, a total of 6,046,356 warrants outstanding as of September 30, 2021, are also considered antidilutive for the periods presented and have not been included in the calculation. The weighted average number of shares takes into account the weighted average effect of changes in treasury shares during the period.

Unaudited Condensed Consolidated Interim Statements of Financial Position

	Notes	September 30, 2022	December 31, 2021
		(EUR'000)	
Assets			
Non-current assets			
Intangible assets		4,939	5,272
Property, plant and equipment		139,345	126,049
Investment in associate		32,001	38,345
Other receivables	**10**	1,895	1,808
Marketable securities	**10**	15,338	107,561
		193,518	**279,035**
Current assets			
Inventories		103,975	75,405
Trade receivables	**10**	6,655	2,200
Income tax receivables		1,630	893
Other receivables	**10**	13,264	20,093
Prepayments		34,568	25,231
Marketable securities	**10**	311,480	235,797
Cash and cash equivalents	**10**	608,330	446,267
		1,079,902	**805,886**
Total assets		**1,273,420**	**1,084,921**
Equity and liabilities			
Equity			
Share capital	**8**	7,658	7,646
Distributable equity		443,894	875,989
		451,552	**883,635**
Non-current liabilities			
Borrowings	**10**	533,145	97,966
Derivative liabilities	**10**	132,731	—
Contract liabilities		13,154	2,964
		679,030	**100,930**
Current liabilities			
Borrowings	**10**	20,096	6,995
Contract liabilities		3,137	2,601
Trade payables and accrued expenses	**10**	86,102	59,417
Other liabilities		26,578	29,952
Income taxes payable		126	198
Provisions		6,799	1,193
		142,838	**100,356**
Total liabilities		**821,868**	**201,286**
Total equity and liabilities		**1,273,420**	**1,084,921**

Unaudited Condensed Consolidated Interim Statements of Changes in Equity

		Distributable Equity					
	Share Capital	Share Premium	Treasury Shares	Foreign Currency Translation Reserve	Share-based Payment Reserve	Accumulated Deficit	Total
				(EUR'000)			
Equity at January 1, 2022	**7,646**	**2,107,739**	**(21,605)**	**3,779**	**199,931**	**(1,413,855)**	**883,635**
Net profit / (loss) for the period	—	—	—	—	—	(375,776)	**(375,776)**
Other comprehensive income / (loss), net of tax	—	—	—	(2,538)	—	—	**(2,538)**
Total comprehensive income / (loss)	**—**	**—**	**—**	**(2,538)**	**—**	**(375,776)**	**(378,314)**
Transactions with Owners							
Share-based payment (Note 7)	—	—	—	—	50,307	—	**50,307**
Acquisition of treasury shares (Note 9)	—	—	(106,099)	—	—	—	**(106,099)**
Capital increase	12	2,011	—	—	—	—	**2,023**
Equity at September 30, 2022	**7,658**	**2,109,750**	**(127,704)**	**1,241**	**250,238**	**(1,789,631)**	**451,552**

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

Unaudited Condensed Consolidated Interim Cash Flow Statements for the Nine Months Ended September 30, 2022 and 2021

	Nine Months Ended September 30,	
	2022	2021
	(EUR'000)	
Operating activities		
Net profit / (loss) for the period	**(375,776)**	**(277,515)**
Reversal of finance income	(73,797)	(44,589)
Reversal of finance expenses	25,381	2,580
Reversal of gain and loss on disposal of property, plant and equipment	22	—
Reversal of tax charge	28	(253)
Increase / (decrease) in provisions	4,954	—
Adjustments for non-cash items:		
Non-cash consideration relating to revenue	(1,913)	(1,749)
Share of profit / (loss) of associate	9,736	(19,434)
Share-based payment	50,307	52,684
Depreciation	12,988	10,784
Amortization	333	333
Changes in working capital:		
Inventories	(28,571)	(55,270)
Receivables	(6,074)	(9,295)
Prepayments	(8,869)	(8,246)
Contract liabilities (deferred income)	10,727	(327)
Trade payables, accrued expenses and other payables	22,528	54,302
Cash flows generated from / (used in) operations	**(357,996)**	**(295,995)**
Finance income received	6,808	2,919
Finance expenses paid	(2,026)	(1,056)
Income taxes received / (paid)	(800)	(207)
Cash flows from / (used in) operating activities	**(354,014)**	**(294,339)**
Investing activities		
Investment in associate	—	(10,187)
Acquisition of property, plant and equipment	(10,707)	(18,907)
Reimbursement from acquisition of property, plant and equipment	9,535	—
Development expenditures (software)	—	(530)
Purchase of marketable securities	(160,839)	(87,544)
Settlement of marketable securities	224,540	118,512
Cash flows from / (used in) investing activities	**62,529**	**1,344**
Financing activities		
Payment of principal portion of lease liabilities	(4,577)	(4,885)
Net proceeds from convertible senior notes	503,281	—
Proceeds from exercise of warrants	2,023	9,209
Net proceeds from follow-on public offerings	—	367,692
Acquisition of treasury shares, net of transaction costs	(105,303)	—
Cash flows from / (used in) financing activities	**395,424**	**372,016**
Increase / (decrease) in cash and cash equivalents	**103,939**	**79,021**
Cash and cash equivalents at January 1	446,267	584,517
Effect of exchange rate changes on balances held in foreign currencies	58,124	29,403
Cash and cash equivalents at September 30	**608,330**	**692,941**
Cash and cash equivalents include:		
Bank deposits	604,018	692,941
Short-term marketable securities	4,312	—
Cash and cash equivalents at September 30	**608,330**	**692,941**

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 approved these unaudited condensed consolidated interim financial statements on November 2, 2022.

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, 2021, 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, 2021. In addition, the accounting policy for convertible senior notes and derivative liabilities, applied for the first time in this reporting period, is described below.

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

Convertible Senior Notes and Derivative Liabilities

Convertible senior notes ("convertible notes") are separated into a financial liability and an embedded derivative component based on the terms and conditions of the contract. The embedded derivative component is accounted for separately if this is not deemed closely related to the financial liability.

The convertible notes include an embedded equity conversion option which is not deemed closely related to the financial liability and is therefore initially recognized and measured separately at fair value as a derivative liability based on the stated terms upon issuance of the convertible notes. The conversion option is classified as a foreign currency conversion option which is not convertible into a fixed number of shares for a fixed amount of cash. Accordingly, the conversion option is recognized and measured as a derivative liability at fair value through profit or loss, with any subsequent remeasurement gains or losses recognized as part of financial income or expenses.

In addition, the convertible notes include a redemption option, which entitle the Company to redeem the notes at a cash amount equal to the principal amount of the convertible notes, plus accrued and unpaid interest. The redemption option is closely related to the financial liability, and therefore is not separately accounted for. The initial carrying amount of the financial liability component including the redemption option is the residual amount of the proceeds, net of allocated transaction costs, after separating the derivative component.

Transaction costs are apportioned between the financial liability and derivative component based on the allocation of proceeds when the instrument is initially recognized. Transaction costs apportioned to the financial liability component form part of the effective interest and are amortized over the expected lifetime of the liability. Transaction costs allocated to the derivative component are expensed as incurred.

The financial liability is subsequently measured at amortized cost until it is extinguished on conversion, optional redemption or upon repayment at maturity. The financial liability is presented as part of borrowings on the statement of financial position.

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 September 30, 2022, to be presented as current liabilities. On September 30, 2022, the carrying amount of convertible notes and derivative liabilities were €434.4 million and €132.7 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, 2021.

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.

Other than as set out below, there have been no other changes to the application of significant accounting judgements, or estimation uncertainties regarding accounting estimates compared to December 31, 2021.

Valuation of Embedded Derivatives

The foreign currency conversion option, embedded in the convertible notes, is accounted for separately as a derivative liability at fair value through profit or loss.

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. Subjective judgements and assumptions, which are subject to estimation uncertainties, need to be exercised in determining the appropriate unobservable input to the valuation model (Level 3 in the fair value hierarchy). This input includes volatility of the Company's share price for a historic period, reflecting the assumption that the historical volatility is indicative of a period similar to the expected lifetime of the option.

Changes in assumptions relating to these factors could affect the reported fair value of derivative liabilities.

Note 4—Significant Events in the Reporting Period

COVID-19 Pandemic

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

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

Conflict in the Region Surrounding Ukraine and Russia

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

Leases

In February 2022, the Company entered into a facility lease in Germany with an enforceable lease term of 15 years, which is expected to commence in 2025. Subject to changes in terms and conditions and development in interest rates, an initial lease liability and corresponding right-of-use asset of €55.2 million is expected to be recognized at the commencement date.

Convertible Senior Notes Offering

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 were $557.9 million (€503.3 million), after deducting the initial purchasers' discounts and commissions and offering expenses.

Further details are disclosed in Note 10, "Financial Assets and Financial Liabilities".

Acquisition of Treasury Shares

The Company used $116.7 million (€105.3 million) of the net proceeds from the offering of the convertible notes to repurchase 1,000,000 ADSs representing the Company's ordinary shares. Total holding of treasury shares is disclosed in Note 9, "Treasury Shares".

Related Party Transactions

The nine months ended September 30, 2022, included invoicing for delivery of future clinical and commercial supply to the Company's associate. At September 30, 2022, €16.1 million is presented as part of contract liabilities on the statement of financial position.

Note 5—Revenue

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(EUR'000)		(EUR'000)	
Revenue from external customers				
Commercial sale of products	12,252	—	18,575	—
Rendering of services	2,401	203	3,385	599
Sale of clinical supply	—	316	4,405	533
Licenses	637	594	1,913	1,749
Total revenue from external customers	**15,290**	**1,113**	**28,278**	**2,881**
Attributable to				
Commercial customers	12,252	—	18,575	—
Collaboration partners and license agreements	3,038	1,113	9,703	2,881
Total revenue from external customers	**15,290**	**1,113**	**28,278**	**2,881**
Specified by timing of recognition				
Recognized over time	2,401	203	3,385	599
Recognized at a point in time	12,889	910	24,893	2,282
Total revenue from external customers	**15,290**	**1,113**	**28,278**	**2,881**
Revenue by geographical location				
Europe	151	—	426	—
North America	12,889	702	24,424	2,076
China	2,250	411	3,428	805
Total revenue from external customers	**15,290**	**1,113**	**28,278**	**2,881**

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 Executive Board, employees, members of the Board of Directors and select consultants, Ascendis Pharma A/S has established warrant programs and, since December 2021, a Restricted Stock Unit program ("RSU program"), which are equity-settled share-based payment transactions.

Share-based Compensation Costs

Share-based compensation costs are determined using the grant date fair value of warrants and Restricted Stock Units ("RSUs") granted 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 nine months ended September 30, 2022 and 2021, share-based compensation costs recognized in the unaudited condensed consolidated interim statement of profit or loss were €13.5 million and €50.3, respectively, and €13.3 million and €52.7 million, respectively.

Restricted Stock Unit Program

RSUs are granted by the Board of Directors in accordance with authorizations given to it by the shareholders of Ascendis Pharma A/S to the Executive Board, select employees and members of the Board of Directors ("RSU-holders") in accordance with the Company's RSU program adopted in December 2021. 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, or waived by the Board of Directors at its discretion.

All RSUs are hedged by treasury shares that have been repurchased in the market. Upon vesting, the Company may at its sole discretion choose to make a cash settlement instead of delivering ADSs.

RSU Activity

The following table specifies the number of RSUs granted, and outstanding RSUs at September 30, 2022:

	Total RSUs
Outstanding at January 1, 2022	**148,148**
Granted during the period	—
Settled during the period	—
Transferred during the period	—
Forfeited during the period	(21,741)
Outstanding at September 30, 2022	**126,407**
Specified by vesting date	
December, 2022	42,131
December, 2023	42,132
December, 2024	42,144
Outstanding at September 30, 2022	**126,407**

The fair value of RSUs at the date of grant was €123.46 for the year ended December 31, 2021, which was the first date of granting RSUs.

Warrant program

Warrants are granted by the Board of Directors in accordance with authorizations given to it by the shareholders of Ascendis Pharma A/S to all employees, members of the Board of Directors and select consultants ("warrantholders"). 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 of Directors. Vested warrants may be exercised in two or four annual exercise periods.

Warrant Activity

The following table specifies the warrant activity for the nine months ended September 30, 2022:

	Total Warrants	Weighted Average Exercise Price EUR
Outstanding at January 1, 2022	**7,085,073**	**80.30**
Granted during the period	258,350	93.94
Exercised during the period	(89,558)	20.40
Forfeited during the period	(316,370)	124.01
Outstanding at September 30, 2022	**6,937,495**	**79.58**
Vested at September 30, 2022	**4,652,454**	**60.69**

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 57,027,240 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 specified below:

	Nominal values	Holding	Holding in % of total outstanding shares
	(EUR'000)	(Number)	
Treasury shares			
At January 1, 2022	**21**	**154,837**	**0.3 %**
Acquired from third-parties	134	1,000,000	—
At September 30, 2022	**155**	**1,154,837**	**2.0 %**

Note 10—Financial Assets and Financial Liabilities

Financial assets and liabilities comprise the following:

	September 30, 2022	December 31, 2021
	(EUR'000)	
Financial assets by category		
Trade receivables	6,655	2,200
Other receivables (excluding income tax and indirect tax receivables)	3,751	12,276
Marketable securities	326,818	343,358
Cash and cash equivalents	608,330	446,267
Financial assets measured at amortized cost	**945,554**	**804,101**
Total financial assets	**945,554**	**804,101**
Classified in the statement of financial position		
Non-current assets	17,232	109,369
Current assets	928,322	694,732
Total financial assets	**945,554**	**804,101**

	September 30, 2022	December 31, 2021
	(EUR'000)	
Financial liabilities by category		
Borrowings		
Convertible senior notes	434,353	—
Lease liabilities	118,888	104,961
Trade payables and accrued expenses	86,102	59,417
Financial liabilities measured at amortized cost	**639,343**	**164,378**
Derivative liabilities	132,731	—
Financial liabilities measured at fair value through profit or loss	**132,731**	—
Total financial liabilities	**772,074**	**164,378**
Classified in the statement of financial position		
Non-current liabilities	665,876	97,966
Current liabilities	106,198	66,412
Total financial liabilities	**772,074**	**164,378**

Marketable Securities

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

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

	September 30, 2022		December 31, 2021	
	Carrying amount	Fair value	Carrying amount	Fair value
	(EUR'000)			
Marketable securities				
U.S. Treasury bills	54,149	54,068	—	—
U.S. Government bonds	124,376	122,435	95,408	95,211
Commercial papers	—	—	2,207	2,207
Corporate bonds	134,960	133,196	226,771	226,379
Agency bonds	13,333	13,144	18,972	18,934
Total marketable securities	**326,818**	**322,843**	**343,358**	**342,731**
Classified based on maturity profiles				
Non-current assets	15,338	14,700	107,561	107,175
Current assets	311,480	308,143	235,797	235,556
Total marketable securities	**326,818**	**322,843**	**343,358**	**342,731**
Specified by rate structure				
Fixed rate	259,768	255,884	323,176	322,556
Floating rate	12,901	12,891	17,975	17,968
Zero-coupon	54,149	54,068	2,207	2,207
Total marketable securities	**326,818**	**322,843**	**343,358**	**342,731**
Specified by investment grade credit rating				
High grade	205,504	203,120	144,307	144,030
Upper medium grade	118,865	117,278	196,909	196,566
Lower medium grade	2,449	2,445	2,142	2,135
Total marketable securities	**326,818**	**322,843**	**343,358**	**342,731**

The Company's portfolio of marketable securities is all denominated in U.S. Dollars. At September 30, 2022, the portfolio had a weighted average duration of 5.2 and 14.4 months for current and non-current positions, respectively, and 5.7 months for the entire portfolio.

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, beginning on October 1, 2022. 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 September 30, 2022, the carrying amount of the convertible notes was €434.4 million, and the fair value was approximately €411.2 million. Fair value cannot be measured based on quoted prices in active markets, or other observable input, and accordingly the fair value was estimated by using an estimated market rate for an equivalent non-convertible instrument (Level 3 in the fair value hierarchy).

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 (Level 3 in the fair value hierarchy). Fair value of the option is calculated, applying the following assumptions: (1) conversion price; (2) the Company's share price; (3) maturity of the option; (4) a risk-free interest rate equaling the effective interest rate on a U.S. government bond with the same lifetime as the maturity of the option; (5) no payment of dividends; and (6) an expected volatility using the Company's share price (49% as of September 30, 2022).

Sensitivity Analysis

Derivative liabilities were recognized in March 2022, at the initial fair value of €142.5 million. For the three and nine months ended September 30, 2022, we recognized a remeasurement loss and gain, respectively of €30.7 million and €9.7 million.

On September 30, 2022, all other inputs and assumptions held constant, a 10% increase in volatility, will increase the fair value of derivative liabilities by approximately €15.5 million and indicates a decrease in profit or loss and equity before tax. Similarly, a 10% decrease in volatility indicates the opposite impact.

Similarly, on September 30, 2022, all other inputs and assumptions held constant, a 10% increase in the share price, will increase the fair value of derivative liabilities by approximately €23.9 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.

Maturity Analysis

Maturity analysis (on an undiscounted basis) for non-derivative financial liabilities recognized in the unaudited condensed consolidated statements of financial position at September 30, 2022, is specified below.

	< 1 year	1-5 years	>5 years	Total contractual cash-flows	Carrying amount
			(EUR'000)		
September 30, 2022					
Borrowings					
Convertible senior notes	13,272	53,088	603,137	669,497	434,353
Lease liabilities	13,605	58,249	69,280	141,134	118,888
Trade payables and accrued expenses	86,102	—	—	86,102	86,102
Total financial liabilities	**112,979**	**111,337**	**672,417**	**896,733**	**639,343**

Note 11—Subsequent Events

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

ASCENDIS PHARMA A/S

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated interim financial statements, including the notes thereto, included with this report and the section contained in our Annual Report on Form 20-F for the year ended December 31, 2021 – "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;
- our expectations regarding the commercial availability of TransCon Growth Hormone, or TransCon hGH, and related patient support services;
- the commercialization of our products and product candidates, if approved;
- our commercialization, marketing and manufacturing capabilities of our products and product candidates and associated devices;
- the scope, progress, results and costs of developing our product candidates or any other future product candidates, and conducting preclinical studies and clinical trials;
- our pursuit of oncology as our second of three independent therapeutic areas of focus, and our development of a pipeline of product candidates related to oncology;
- our expectations regarding the potential market size and the size of the patient populations for our products and product candidates, if approved for commercial use;
- our expectations regarding the potential advantages 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 file 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, TransCon hGH and our other product candidates and technologies, including global commercialization strategies;

- the scope of protection we are able to establish and maintain for intellectual property rights covering TransCon hGH and our other product candidates;
- 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 biopharmaceutical company;
- our use of our TransCon technologies to create new and potentially best-in-class therapies;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our financial performance;
- developments and projections relating to our market conditions, competitors and industry;
- the impact of international economic, political, legal, compliance, social and business factors, including inflation; and
- the effects on our business of the worldwide COVID-19 pandemic and the ongoing conflict in the region surrounding Ukraine and Russia.

These forward-looking statements are based on senior management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this report may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section in our Annual Report on Form 20-F for the year ended December 31, 2021 — "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.

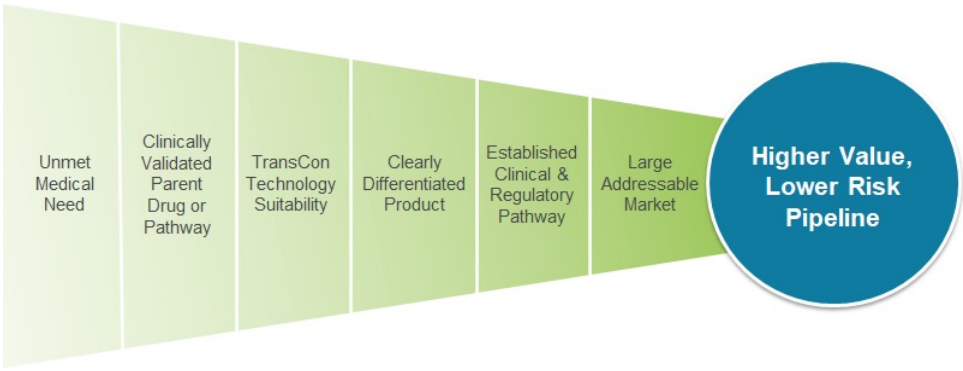
You should read this report and the documents that we reference in this report and have filed as exhibits to this report completely and with the understanding that our actual future results may be materially different from what we expect. You should also review the factors and risks we describe in the 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

Ascendis Pharma is applying its innovative TransCon 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. Ascendis is headquartered in Copenhagen, Denmark, and has additional facilities in Heidelberg and Berlin, Germany; Palo Alto and Redwood City, California; and Princeton, New Jersey.

We have applied these TransCon technologies in combination with a clinically-validated parent drug or pathway using our algorithm for product innovation with the goal of creating product candidates with the potential to be best-in-class in endocrinology rare diseases and oncology. In addition, we plan to apply this algorithm for product innovation and selection in new therapeutic areas. We believe our approach to product innovation may reduce the risks associated with traditional drug development, and that our TransCon technologies have been validated by non-clinical and clinical programs completed to date.

Ascendis Algorithm for Product Innovation



Through our approach, we may benefit from established clinical safety and efficacy data, which we believe increases the probability of success. As presented above, our algorithm for product innovation focuses on identifying indications that have an unmet medical need, have a clinically-validated parent drug or pathway, are suitable to our TransCon technologies, have potential for creating a clearly differentiated product, have an established development pathway and have a large potentially addressable market.

We currently have one marketed product and a diversified portfolio of five product candidates in clinical development in the areas of endocrinology rare diseases and oncology. We are also evaluating additional therapeutic areas and indications.

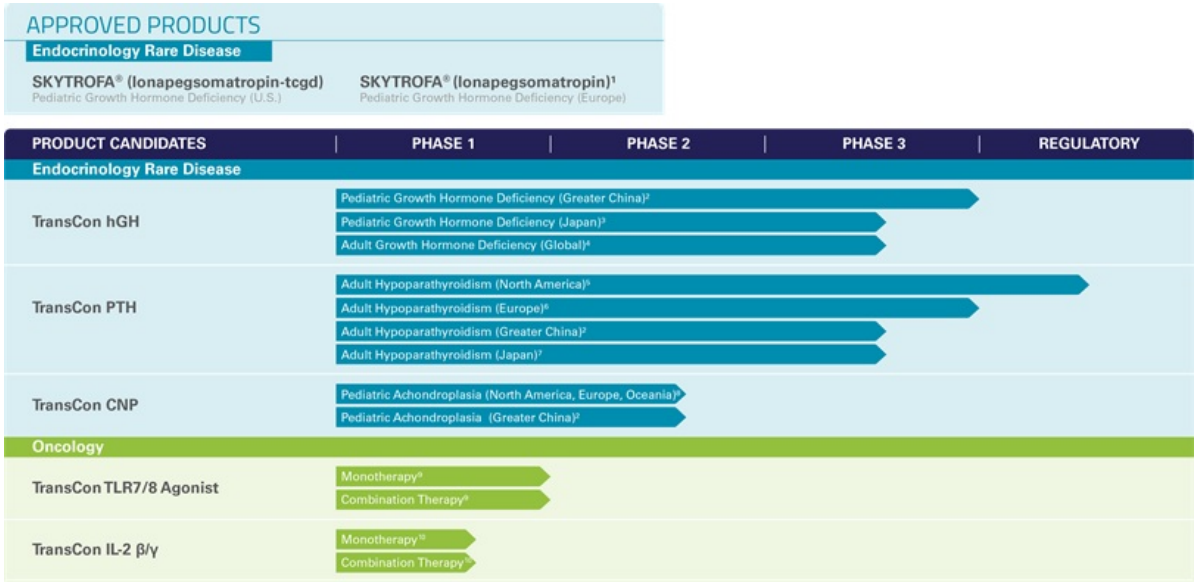
- First Approved Product – Our first product, SKYTROFA® (lonapegsomatropin-tcgd), developed as TransCon Growth Hormone ("TransCon hGH"), received regulatory approval in the United States ("U.S.") for the treatment of pediatric patients one year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone, also known as growth hormone deficiency ("GHD"). SKYTROFA is now commercially available for prescription in the U.S. As of September 30, 2022, the cumulative number of new patient prescriptions for SKYTROFA increased to over 2,400. TransCon hGH is also approved in the European Union ("EU") under the name Skytrofa® (lonapegsomatropin) for the treatment of children and adolescents aged from 3 years up to 18 years with growth failure due to insufficient endogenous growth hormone secretion. In Europe, we plan to commercially launch Skytrofa in Germany during 2023.
- Endocrinology Rare Disease Pipeline – We are developing three product candidates in our endocrinology rare disease portfolio spanning multiple clinical programs. These include TransCon hGH for pediatric GHD in Japan; TransCon hGH for adults with GHD; TransCon hGH for Turner Syndrome; TransCon PTH for adults with hypoparathyroidism; and TransCon CNP for achondroplasia. In addition, we are planning new clinical trials including TransCon PTH for children with hypoparathyroidism; once-weekly TransCon PTH for hypoparathyroidism; and TransCon CNP for infants (age 0-2 years) with achondroplasia. VISEN Pharmaceuticals has been granted the exclusive rights to develop TransCon hGH, TransCon PTH and TransCon CNP in Greater China.

- Oncology Pipeline – In oncology, we are leveraging our TransCon technologies in effort to enhance anti-tumor effects of clinically-validated parent drugs and pathways and to provide sustained modulation of tumor microenvironments and activate cytotoxic immune cells. We have initiated clinical development of two product candidates: TransCon TLR7/8 Agonist, an investigational, long-acting prodrug of resiquimod, a small molecule agonist of Toll like receptors ("TLR") 7 and 8 for intratumoral delivery and TransCon IL-2 ß/g for systemic delivery, which is designed for prolonged exposure to an IL-2 variant that selectively activates the IL-2Rß/g, with minimal binding to IL-2Rα. Our clinical development program for these product candidates also includes evaluation of them as a potential combination therapy.

Global Commercialization Strategy

We plan to establish a global commercial presence to deliver potential best-in-class TransCon product candidates to address patients' unmet medical needs. We have established a multi-faceted organization in the U.S. to support the ongoing commercialization of SKYTROFA which will also serve as the foundation for future endocrinology rare disease product launches in the U.S. We plan to expand our presence in Europe by building integrated organizations in select countries and through established distribution channels in others. In other markets, we plan to establish commercial presence through partners with local expertise and infrastructure.

TransCon Product and Product Candidate Pipeline

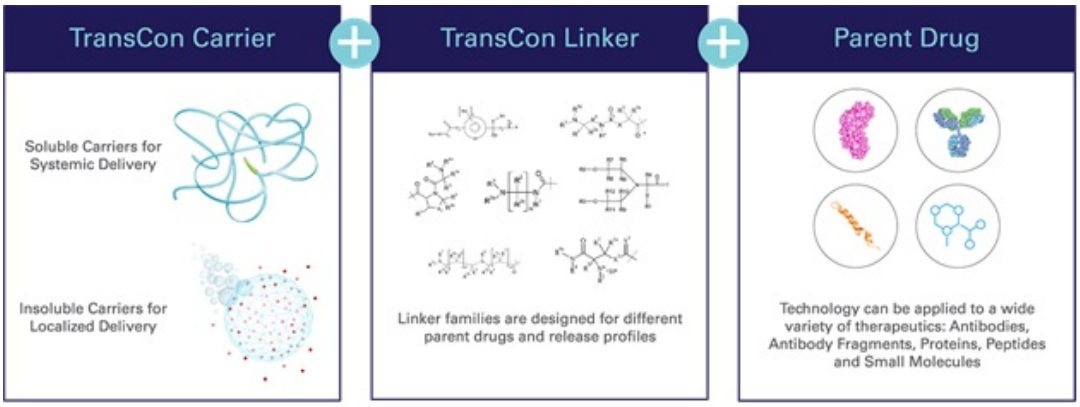


1. Not yet marketed in the EU.
2. In development in Greater China through strategic investment in VISEN Pharmaceuticals.
3. Japanese riGHt Trial.
4. Global foresiGHt Trial.
5. FDA set a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2023.
6. European MAA submission planned for Q4 2022.
7. Japanese PaTHway Japan Trial.
8. North America, Europe, and Oceania ACcomplisH Trial.
9. transcendIT-101 Trial.
10. IL-ßeliege Trial.

TransCon Technologies

Our TransCon technologies are designed to combine the benefits of conventional prodrug and sustained release technologies to solve the fundamental limitations seen in other approaches to extending duration of a drug's action in the body with the goal of developing highly differentiated product candidates based on potential safety and efficacy. 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, the unmodified parent drug is released in a predictable manner. Depending upon the type of TransCon carrier we employ, we can design our TransCon prodrugs for sustained localized or systemic delivery.



TransCon Products Candidates – Endocrinology Rare Disease

TransCon Growth Hormone

TransCon hGH is a long-acting prodrug of somatropin ("hGH") 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 used in extensively proven daily hGH therapy.

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

Global annual sales from currently marketed hGH products are estimated at approximately $4 billion. We believe a significant market opportunity exists for a long-acting version of hGH with comparable efficacy, safety, and tolerability to daily hGH products.

Recent Developments

In June 2022, we submitted a trial protocol to the FDA to evaluate TransCon hGH in Turner Syndrome.

In May 2022, VISEN Pharmaceuticals announced results from its Phase 3 trial of once-weekly TransCon hGH in children with GHD in China. The trial demonstrated results that were consistent with our Phase 3 heiGHt Trial. VISEN Pharmaceuticals' Phase 3 trial achieved its primary endpoint, with pediatric GHD patients treated with once-weekly TransCon hGH demonstrating greater annualized height velocity at 52-weeks compared to patients treated with daily growth hormone.

In January 2022, the European Commission granted marketing authorization for Skytrofa 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 U.S. Food and Drug Administration ("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. Once-weekly SKYTROFA is the first FDA approved product that delivers somatropin, or growth hormone, by sustained release over one week.

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

In October 2019, we received Orphan Designation ("OD") from the European Commission for TransCon hGH for GHD. OD is granted to therapies aimed at the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating, affects no more than five in 10,000 persons in the EU, or the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or if such a method exists, the product would provide significant additional benefit over existing therapies). We received Orphan Drug Designation ("ODD") from the FDA for TransCon hGH as a treatment for GHD in April 2020.

TransCon Growth Hormone (hGH) for Other Indications

We continue to enroll patients in the foresiGHt Trial, a global Phase 3 study with the aim to demonstrate the metabolic benefits of lonapegsomatropin in adults. We are now targeting completion of enrollment in the foresiGHt Trial in the fourth quarter of 2022.

In the second quarter of 2022, we submitted a protocol to the FDA to evaluate TransCon hGH for Turner Syndrome. In addition, we are also considering other potential indications for TransCon hGH where a long-acting hGH therapy may offer a best-in-class option for patients with rare growth disorders.

TransCon Parathyroid Hormone

TransCon Parathyroid Hormone (“PTH”) is an investigational long-acting prodrug of PTH that is designed as a novel replacement therapy for PTH to achieve and maintain a steady concentration of PTH in the bloodstream within the normal range, at levels similar to those observed in healthy individuals. TransCon PTH is designed to restore physiologic levels of PTH, 24 hours per day, thereby addressing the underlying cause of disease.

Hypoparathyroidism is a rare endocrine disorder characterized by insufficient levels of parathyroid hormone. Hypoparathyroidism affects approximately 200,000 patients in the United States, Europe, and Japan, most of whom develop the condition following damage to or accidental removal of the parathyroid glands during thyroid surgery. Conventional therapy with calcium supplements and active vitamin D (also called calcitriol) does not effectively address the short-term symptoms, long-term complications, or quality-of-life impacts of hypoparathyroidism.

Short-term symptoms include weakness, severe muscle cramps (tetany), abnormal sensations such as tingling, burning and numbness (paresthesia), memory loss, impaired judgment, and headache. Patients often experience decreased quality of life, and, over the long term, this complex disorder can increase risk of major complications, such as calcium deposits in the brain, blood vessels, eye, and other soft tissues – including the kidneys, which can lead to impaired renal function. Hypoparathyroidism remains among the few hormonal insufficiency states without a replacement therapy that restores the missing hormone at physiologic levels.

The latest clinical practice guideline addressing the prevention, diagnosis, and management of hypoparathyroidism was published in September 2022 in the Journal of Bone and Mineral Research and authored by leading clinicians from North America, Europe, and Asia. TransCon PTH attributes and study results were included in the guidelines. The authors suggest consideration of parathyroid hormone (PTH) replacement therapy in patients whose hypoparathyroidism is inadequately controlled with conventional therapy. Inadequate control is considered to be any one of the following: symptomatic hypocalcemia, hyperphosphatemia, renal insufficiency, hypercalciuria, or poor quality of life. In addition, the guidelines indicate that individuals with poor compliance, malabsorption or who are intolerant of large dose of calcium and active vitamin D may also benefit from PTH replacement therapy. Based on these current guidelines, we believe PTH replacement therapy could be applicable to most patients with hypoparathyroidism.

Recent Developments

In October 2022, FDA accepted our New Drug Application ("NDA") for TransCon PTH in adult patients with hypoparathyroidism for Priority Review and has set a Prescription Drug User Fee Act target action date of April 30, 2023. The FDA indicated that, at this time, it had no plans for an advisory committee meeting to discuss the application.

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 seen in 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. The data also showed continued restoration of skeletal bone mineral density (BMD) toward sex- and age-expected norms for study participants treated with TransCon PTH, which augments turnover of stagnant bone. Participants with more years of hypoparathyroidism duration had higher mean baseline BMD Z-scores and larger decreases in BMD Z-scores through Week 110, trending toward age- and sex-matched norms. PTH replacement therapy with TransCon PTH was well-tolerated through Week 110, with continued normalization of mean urine calcium and no discontinuations from the trial due to adverse events.

As of September 30, 2022, 57 out of the 59 adult patients continued in the open-label extension portion of the PaTH Forward Trial, where they receive an individualized maintenance dose of TransCon PTH (6 to 30 µg per day). In addition, all 57 subjects have exceeded two 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 August 2022, we submitted a New Drug Application to the U.S. FDA for TransCon PTH for adults with hypoparathyroidism.

In March 2022, we announced that top-line data from the randomized, double-blind, placebo-controlled portion of its 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 – 2 from the placebo arm and 1 from the TransCon PTH arm. TransCon PTH-treated patients showed a mean decrease in 24-hour urine calcium excretion into the normal range.

Following an initial blinded study period of 26 weeks all 79 patients completing the blinded period opted to receive treatment with TransCon PTH in the ongoing open-label extension portion of the study for up to 3 years (156 weeks). As of September 30, 2022, 77 out of 79 patients continued in the open label extension portion of the PaTHway Trial.

In November 2021, we announced week 84 top-line data from the Phase 2 PaTH Forward Trial. Week 84 results from the open-label extension portion of the PaTH Forward trial demonstrated:

- Mean serum calcium levels remained stable and in the normal range.
- All study subjects discontinued active vitamin D supplements in the earliest weeks of the trial and have remained off it since then. In addition, 93% of subjects were taking calcium supplements <600 mg per day.
- Mean urinary calcium excretion remained stable and in the normal range.
- TransCon PTH was well-tolerated at all doses administered. No treatment-related serious or severe adverse events occurred, and no treatment-emergent adverse events ("TEAEs") led to discontinuation of study drug.
- Injections were well-tolerated using pen injector planned for commercial presentation.
- At week 58, quality-of-life and bone mineral density data were collected. The data demonstrated:
    - All mean summary and subdomain SF-36 Health Survey scores continued normalization between week 26 and week 58 despite all mean scores starting below norms at baseline.
    - Bone mineral density Z-scores trended towards normalization and stabilization over 58 weeks in PaTH Forward.

In the second quarter of 2021, we submitted a CTN to the MHLW for PaTHway Japan Trial, a Phase 3 trial to evaluate the safety, tolerability, and efficacy of TransCon PTH. In July 2021, the Japanese Pharmaceuticals and Medical Devices Agency accepted the CTN for the PaTHway Japan Trial, a single-arm, Phase 3 trial of TransCon PTH in a minimum of 12 Japanese subjects with hypoparathyroidism. Subjects will start with an 18 µg dose of TransCon PTH and be followed over a 26-week period during which they will be titrated to an optimal dose. The minimum enrollment target of 12 patients was achieved in April 2022.

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

In June 2018, we were granted orphan drug designation by the FDA for TransCon PTH for the treatment of hypoparathyroidism.

TransCon C-Type Natriuretic Peptide

TransCon C-Type Natriuretic Peptide (“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. TransCon CNP is designed to provide effective shielding of CNP from neutral endopeptidase degradation in subcutaneous tissue and the blood compartment, minimize binding of CNP to the NPR-C receptor to decrease clearance, reduce binding of CNP to the NPR-B receptor in the cardiovascular system to avoid hypotension, and release unmodified CNP, which is small enough in size to allow effective penetration into growth plates. We believe TransCon CNP may offer advantages over shorter-acting CNP and CNP analogs in development that can result in high Cmax levels which may cause adverse cardiovascular events. In addition, we expect a more constant CNP exposure at a lower Cmax level to correlate with better therapeutic outcomes in treating children with achondroplasia.

Achondroplasia is the most common form of dwarfism, occurring in about one in 10,000 to 30,000 newborns or approximately 250,000 worldwide. Achondroplasia results in severe skeletal complications and comorbidities, including spinal stenosis due to premature fusion of the foramen magnum, sleep apnea, and chronic ear infections. Achondroplasia is caused by an autosomal dominant activating mutation in fibroblast growth factor receptor 3 (“FGFR3”) that leads to an imbalance in the effects of the FGFR3 and C-type natriuretic peptide (CNP) signaling pathways.

In October 2022, we submitted protocols to initiate ApproaCH, a new global randomized, double-blind, placebo-controlled Phase 2b trial in children ages 2-11 years with achondroplasia.

In December 2021, we announced that enrollment in ACcomplisH Trial was completed. The ACcomplisH Trial, a randomized, double-blind, placebo-controlled, sequential rising dose, Phase 2 trial to evaluate the safety and efficacy of TransCon CNP in approximately 60 children with achondroplasia (ages two to ten years). Subjects are randomized to receive either TransCon CNP or placebo in a 3:1 ratio. The primary efficacy endpoint is annualized height velocity at twelve months. Key secondary and additional endpoints include body proportionality and change in BMI, both evaluated after twelve months of weekly TransCon CNP treatment, and patient reported outcome measures. As of September 30, 2022, all 57 patients in the ACcomplisH trial continue in the open-label extension portion of the ACcomplisH Trial on drug at the 100 microgram per kilogram dose.

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

In July 2020, we received orphan designation from the EC for TransCon CNP for treatment of achondroplasia.

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

TransCon Products Candidates – Oncology

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

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

Our TransCon product candidates in oncology are designed to provide sustained systemic or intratumoral administration, which we believe could provide potent and durable anti-tumor efficacy. Our nonclinical studies have showed sustained activation of cytotoxic immune cells that resulted in robust anti-tumor responses by TransCon product candidates using infrequent administration.

TransCon TLR7/8 Agonist

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 and to have a low risk of systemic toxicity for weeks or months following a single intratumoral injection.

In October 2022, we announced completion of the dose-escalation portion and recommendation of the Phase 2 dose in transcendIT-101, 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. In the next phase of the trial, the recommended Phase 2 dose of TransCon TLR7/8 Agonist will be evaluated in four cohorts focused on cancers where increased Toll-like receptor ("TLR") activity has potential to improve adaptive immune activation and host defense against cancers. The cohorts include head and neck squamous-cell carcinoma; other HPV-associated cancers; melanoma; and cutaneous squamous cell carcinoma. In this portion of the study, all participants will be treated every three weeks with intratumoral TransCon TLR7/8 Agonist in combination with intravenous pembrolizumab. Limits on prior lines of therapy vary by cohort.

TransCon IL-2 ß/g

TransCon IL-2 ß/g is an investigational long-acting prodrug designed to improve cancer immunotherapy through sustained release of an IL-2 variant that selectively activates the IL-2Rß//g, with minimal binding to IL-2Rα. The Phase 1/2 IL-ßeliege Trial evaluating TransCon IL-2 ß/g monotherapy in patients with advanced cancer is enrolling patients in dose escalation cohorts. During the second quarter of 2022, we dosed the first patient in the combination dose escalation cohort for TransCon IL-2 ß/g and checkpoint inhibitor, in the IL-ßeliege Trial.

We are evaluating additional TransCon product candidates in nonclinical research studies with potential to enhance anti-tumor immune responses for the treatment of multiple tumor types. We are exploring product candidates using both systemic and intratumoral administration as monotherapies and as components of combination regimens. We believe these programs have the potential to make a positive impact to the lives of many patients with cancer.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2022 and 2021 (unaudited)

Summary

Commercialization of SKYTROFA continues following its launch in the U.S. in the fourth quarter of 2021. SKYTROFA revenue reached €12.3 million for the third quarter. As of September 30, 2022, the cumulative number of new patient prescriptions for SKYTROFA increased to over 2,400.

Selling, general and administrative expenses have increased, primarily reflecting higher commercial costs in the U.S. following the launch of SKYTROFA and planning for future product launches. Financial income and expenses are significantly affected by development in the U.S. Dollar compared to the Euro, where the strengthening of the U.S. Dollar remains the primary driver for the development in finance income for the three and nine months ended September 30, 2022.

At the end of March 2022, we completed a $575.0 million convertible senior notes offering, strengthening our balance sheet. With €935.1 million in cash, cash equivalents and marketable securities, we believe we are well-positioned to fulfill Vision 3x3 and build a leading, fully integrated, global, biopharma company.

The conversion option embedded in the convertible notes is recognized and measured at fair value, where we recognized significant non-cash fair value adjustments through finance expenses and finance income for the three and nine months ended September 30, 2022, respectively. Similarly, subsequent reporting periods may result in significant non-cash finance income or expenses, as applicable. For further description, please refer to “Equity Risk” in section “Qualitative Disclosures about Market Risk” and Note 10, “Financial Assets and Financial Liabilities”.

We realized a net loss of €375.8 million for the nine months ended September 30, 2022, compared to €277.5 million for the same period last year.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(EUR’000)		(EUR’000)	
Statement of Profit or Loss				
Revenue	15,290	1,113	28,278	2,881
Cost of sales	1,693	—	7,025	—
Gross profit / (loss)	**13,597**	**1,113**	**21,253**	**2,881**
Research and development costs	97,431	58,761	271,006	230,216
Selling, general and administrative expenses	60,671	39,284	164,675	111,876
Operating profit / (loss)	**(144,505)**	**(96,932)**	**(414,428)**	**(339,211)**
Share of profit / (loss) of associate	(3,696)	(3,855)	(9,736)	19,434
Finance income	20,326	21,321	73,797	44,589
Finance expenses	41,247	877	25,381	2,580
Profit / (loss) before tax	**(169,122)**	**(80,343)**	**(375,748)**	**(277,768)**
Tax on profit / (loss) for the period	167	(5)	(28)	253
Net profit / (loss) for the period	**(168,955)**	**(80,348)**	**(375,776)**	**(277,515)**

Revenue

The following table summarizes our revenue for the three and nine months ended September 30, 2022 and 2021.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(EUR'000)		(EUR'000)	
Revenue from external customers				
Commercial sale of products	12,252	—	18,575	—
Rendering of services	2,401	203	3,385	599
Sale of clinical supply	—	316	4,405	533
Licenses	637	594	1,913	1,749
Total revenue from external customers	**15,290**	**1,113**	**28,278**	**2,881**

Revenue increased by €14.2 million and €25.4 million, respectively, for the three and nine months ended September 30, 2022, which was primarily attributable to commercial sale of SKYTROFA, for which we began shipping products in the fourth quarter of 2021.

Cost of Sales

Cost of sales comprise cost of commercial products sold, and cost of clinical supply delivered to VISEN Pharmaceuticals, primarily related to the first three months of 2022. Since we first began shipping products to commercial customers in the fourth quarter of 2021, no cost of sales was recognized for the comparative periods.

Research and Development Costs

The following table specifies external project costs on the development pipeline and other research and development ("R&D") costs.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(EUR'000)		(EUR'000)	
External project costs				
TransCon hGH	27,770	(3,154)	70,637	52,045
TransCon PTH	11,397	8,650	33,975	25,192
TransCon CNP	9,518	14,048	26,631	30,244
TransCon IL-2 ß/γ	3,536	3,169	6,891	10,267
TransCon TLR7/8	7,621	4,329	15,268	10,092
Other project costs	1,769	579	4,054	1,367
Total external project costs	**61,611**	**27,621**	**157,456**	**129,207**
Other research and development costs				
Employee costs	26,334	25,248	88,105	83,719
Other costs	6,803	3,378	17,337	9,871
Depreciation	2,683	2,514	8,108	7,419
Total other research and development costs	**35,820**	**31,140**	**113,550**	**101,009**
Total research and development costs	**97,431**	**58,761**	**271,006**	**230,216**

R&D costs increased by €38.7 million and €40.8 million, respectively, for the three and nine months ended September 30, 2022, primarily due to the impact from reversal of write-down (income) of pre-launch inventories of €53.7 million in the comparative periods, following receipt of the marketing approval for SKYTROFA on the U.S. market in August 2021. The increase in total R&D costs is also driven by manufacturing of pre-launch inventories for TransCon PTH with a total amount of €5.3 million and €11.7 million for the three and nine months ended September 30, 2022, respectively, and an increase in employee and other costs attributable to organizational growth.

Following the U.S. FDA approval of SKYTROFA, manufacturing of commercial product supply is recognized as inventory, whereas such costs were recognized as research and development costs prior to the U.S. FDA approval in August 2021.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by €21.4 million and €52.8 million, respectively, for the three and nine months ended September 30, 2022, which was primarily attributable to the launch of SKYTROFA in the U.S. and preparation for future product launches.

Net Profit / (Loss) of Associate

Net loss of associate was €3.7 million and €9.7 million, respectively, for the three and nine months ended September 30, 2022, compared to a net loss of €3.9 million and a net profit of €19.4 million, respectively, for the three and nine months ended September 30, 2021. The net loss represents our share of the net result from VISEN Pharmaceuticals. For the nine months ended September 30, 2021, the net profit of associate included a non-cash gain of €42.3 million as a result of the Series B financing in VISEN Pharmaceuticals in January 2021.

Finance Income and Finance Expenses

Net finance income decreased by €41.4 million for the three months ended September 30, 2022, which primarily relates to remeasurement loss on derivative liabilities of €30.7 million and interest and amortization charges on the convertible notes of €9.2 million.

Net finance income increased by €6.4 million for the nine months ended September 30, 2022, which primarily relates to net foreign exchange rate gains when translating and reporting U.S. Dollar denominated cash, cash equivalents and marketable securities, and remeasurement gain on derivative liabilities of €9.7 million, partly offset by interest and amortization charges on the convertible notes of €17.3 million and €4.2 million transaction costs representing the part of the total transaction costs that were attributable to the derivative component of the convertible notes financing in March 2022.

Impact from COVID-19 Pandemic

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

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

As a result of governmental restrictions, field-based sales personnel primarily have worked under a remote engagement model with healthcare professionals and patient care organizations, and similarly, some patients have not been able to see their physicians. As restrictions cease, field-based sales personnel have begun in person engagements when interacting with healthcare professionals and patient care organizations, as well as patients having easier access to their physicians. The impact on the commercial product revenue is uncertain and difficult to quantify.

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

For additional description of COVID-19 related risks, please refer to “Item 3D. Risk Factors”, set forth in our 2021 Annual Report on Form 20-F.

Liquidity and Capital Resources

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

As of September 30, 2022, these amounted to €935.1 million, specified as follows:

	Carrying amount	Fair value
	(EUR'000)	
September 30, 2022		
Liquidity and capital resources		
Marketable securities	326,818	322,843
Cash and cash equivalents	608,330	608,330
Total liquidity and capital resources	**935,148**	**931,173**
Classification in consolidated statement of financial position		
Non-current assets	15,338	14,700
Current assets	919,810	916,473
Total liquidity and capital resources	**935,148**	**931,173**

As of September 30, 2022, marketable securities had a weighted average duration of 5.2 and 14.4 months, for current (i.e., those maturing within twelve months after the reporting date) and non-current positions, respectively. The entire portfolio of marketable securities (current and non-current) had a weighted average duration of 5.7 months.

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.

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

- In 2016, with net proceeds of $127.1 million (or €116.6 million);
- In 2017, with net proceeds of $145.2 million (or €123.1 million);
- In 2018, with net proceeds of $242.5 million (or €198.6 million);
- In 2019, with net proceeds of $539.4 million (or €480.3 million);
- In 2020, with net proceeds of $654.6 million (or €580.5 million); and
- In 2021, with net proceeds of $436.5 million (or €367.9 million).

In March 2022, we 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 and are redeemable by us no earlier than on or after April 7, 2025. Unless earlier converted or redeemed, the convertible notes will mature on April 1, 2028. For further description of the convertible notes, and a maturity analysis (on an un-discounted basis) for non-derivative financial liabilities, recognized in the unaudited condensed consolidated statements of financial position as of September 30, 2022, please refer to Note 10, "Financial Assets and Financial Liabilities".

We used $116.7 million (€105.3 million) of the net proceeds from the offering in March 2022 to repurchase 1,000,000 ADSs representing the Company's ordinary shares. Total holding of treasury shares is disclosed in Note 9, "Treasury Shares".

Our operational expenditures are primarily related to research and development activities and general and administrative activities to support our therapeutic areas within endocrinology and oncology. In addition, expenditures relate to expanding our sales and marketing capabilities and inventories to support the commercialization of SKYTROFA in the U.S. and planned European launch in 2023, as well as preparation for future product launches.

We manage our liquidity risk by maintaining adequate cash reserves and banking facilities, and by matching the maturity profiles of financial assets including marketable securities, with cash-forecasts including payment profiles on liabilities. We monitor the risk of a shortage of funds 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 cash, cash equivalents and marketable securities as of September 30, 2022, 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.

For additional description of our cash requirements, expense structure and commitments, please refer to “Item 5B. Liquidity and Capital Resources”, set forth in our 2021 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 TransCon hGH and with our other 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 TransCon hGH and for our other 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 collaboration partners (if any), which in turn is impacted by the financial standing of any such collaboration partners;
- the progress, timing, scope, results and costs of our preclinical studies and clinical trials and manufacturing activities for our product candidates that have not been licensed, including the ability to enroll patients in a timely manner for clinical trials;
- the time and cost necessary to obtain regulatory approvals for our product candidates and the costs of post-marketing studies that could be required by regulatory authorities;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the number and scope of preclinical and discovery programs that we decide to pursue or initiate;
- the potential acquisition and in-licensing of other technologies, products or assets;
- the time and cost necessary to respond to technological and market developments, including further development of our TransCon technologies;
- the achievement of development, regulatory and commercial milestones resulting in the payment to us from collaboration partners of contractual milestone payments and the timing of receipt of such payments, if any;
- our progress in the successful commercialization of TransCon hGH and of our other product candidates, if approved, and our efforts to develop and commercialize our other existing product candidates; and
- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation, including costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of our product candidates.

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

The following table summarizes the cash flows for each of the unaudited nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		
	2022	2021	Change
		(EUR'000)	
Cash flow from / (used in)			
Operating activities	(354,014)	(294,339)	(59,675)
Investing activities	62,529	1,344	61,185
Financing activities	395,424	372,016	23,408
Net increase / (decrease) in cash and cash equivalents	**103,939**	**79,021**	**24,918**

Cash Flow from / (Used in) Operating Activities

Cash flow used in operating activities represents all cash flows other than those classified as either investing or financing activities. Cash flow used in operating activities includes net loss for the period adjusted for non-cash net financial income and taxes, changes to provisions, other non-cash items, and net change in working capital items.

The €59.7 million increase in cash flow used in operating activities for the nine months ended September 30, 2022, compared to the same period last year, was attributable to increase in net loss for the period adjusted for non-operating financial income and expense, taxes, and non-cash items. In addition, working capital items contributed positively to operating cash flows by €8.6 million, primarily due to advance invoicing for future delivery of clinical and commercial supply, partly off-set by an overall increase in working capital activity related to commercial and R&D activities.

Cash Flow from / (Used in) Investing Activities

The €61.2 million increase in cash flow from investing activities for the nine months ended September 30, 2022, compared to the same period last year, was primarily attributable to:

- additional net settlements of marketable securities of €32.7 million in line with our liquidity management strategy;
- reimbursement from property, plant and equipment of €9.6 million primarily related to leasehold improvements for our U.S. facilities, which was constructed in 2021; and
- the Series B investment in VISEN Pharmaceuticals of €10.2 million made in January 2021, which reduced the cash flow for the nine months ended September 30, 2021.

Cash Flow from / (Used in) Financing Activities

The €23.4 million increase in cash flow from financing activities for the nine months ended September 30, 2022, compared to the same period last year, was primarily attributable to proceeds from issuance of convertible notes net of paid transaction costs of €503.3 million compared to our follow-on public offering in September 2021 of €367.7 million, partly offset by acquisition of treasury shares of €105.3 million.

Off-balance Sheet Arrangements

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

Qualitative Disclosures about Market Risk

Our activities expose us to financial risks of changes in foreign currency exchange rates and interest rates. We do not enter into derivative financial instruments to manage our exposure to such risks. Further, we are exposed to credit risk, 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, 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.

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. The banks are reviewed on a regular basis and deposits may be transferred during the year to mitigate credit risk. In order to mitigate the concentration of credit risks on bank deposits and to preserve capital, a portion of the bank deposits have been placed into primarily U.S treasury bills, U.S. government bonds and corporate bonds. Our investment policy, approved by the Board of Directors, only allows investment in marketable securities having investment grade credit-ratings, assigned by international credit-rating agencies. Accordingly, the risk from probability of default is low. On each reporting date, we consider the risk of expected credit loss on bank deposits and marketable securities, including the hypothetical impact arising from the probability of default, which is considered in conjunction with the expected loss caused by default by banks or securities with similar credit-ratings and attributes. In line with previous periods, this assessment did not reveal a material impairment loss, and accordingly no provision for expected credit loss has been recognized.

Equity Risk

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

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