
**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 May, 2021

Commission File Number: 001-36815

Ascendis Pharma A/S

(Exact Name of Registrant as Specified in Its Charter)

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

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

Form 20-F Form 40-F

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

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

INCORPORATION BY REFERENCE

Exhibits 99.1 and 99.2 of this report on Form 6-K shall be deemed to be incorporated by reference into the registration statements on Form S-8 (Registration Numbers 333-203040, 333-210810, 333-211512, 333-213412, 333-214843, 333-216883, 333-228576 and 333-254101) and Form F-3 (Registration Numbers 333-209336, 333-211511, 333-216882, 333-223134 and 333-225284) of Ascendis Pharma A/S (the “Company”) (including any prospectuses forming a part of such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Furnished as exhibits to this Report on Form 6-K is information regarding the Company’s financial results for the fiscal quarter ended March 31, 2021.

Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Unaudited Condensed Consolidated Interim Financial Statements.
99.2	Management’s Discussion and Analysis of Financial Condition and Results of Operations.
99.3	Press Release dated May 27, 2021.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.IAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

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.

Date: May 27, 2021

Ascendis Pharma A/S

By: /s/ Michael Wolff Jensen

Michael Wolff Jensen

Chairman and Senior Vice President, Chief Legal Officer

ASCENDIS PHARMA A/S

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

	Notes	Three Months Ended March 31	
		2021	2020
(EUR'000)			
Statement of Profit or Loss			
Revenue	5	746	2,225
Research and development costs	7	(88,149)	(57,515)
Selling, general, and administrative expenses	7	(37,247)	(17,915)
Operating profit / (loss)		(124,650)	(73,205)
Share of profit / (loss) of associate		28,106	(1,515)
Finance income		34,430	11,773
Finance expenses		(869)	(447)
Profit / (loss) before tax		(62,983)	(63,394)
Tax on profit / (loss) for the period		191	77
Net profit / (loss) for the period		(62,792)	(63,317)
Attributable to owners of the Company		(62,792)	(63,317)
Basic and diluted earnings / (loss) per share		€(1.17)	€(1.32)
Number of shares used for calculation (basic and diluted) ⁽¹⁾		53,759,952	47,985,837
(EUR'000)			
Statement of Comprehensive Income			
Net profit / (loss) for the period		(62,792)	(63,317)
Other comprehensive income / (loss)			
<i>Items that may be reclassified subsequently to profit or loss:</i>			
Exchange differences on translating foreign operations		1,842	86
Other comprehensive income / (loss) for the period, net of tax		1,842	86
Total comprehensive income / (loss) for the period, net of tax		(60,950)	(63,231)
Attributable to owners of the Company		(60,950)	(63,231)

- (1) A total of 6,109,942 warrants outstanding as of March 31, 2021 can potentially dilute earnings per share in the future but have not been included in the calculation of diluted earnings per share because they are antidilutive for the periods presented. Similarly, a total of 5,941,364 warrants outstanding as of March 31, 2020 are also considered antidilutive for the periods presented and have not been included in the calculation.

Unaudited Condensed Consolidated Interim Statements of Financial Position

	Notes	March 31, 2021	December 31, 2020
		(EUR'000)	
Assets			
Non-current assets			
Intangible assets		5,606	5,717
Property, plant and equipment		114,196	108,112
Investment in associate		50,035	9,176
Other receivables		1,779	1,375
Marketable securities	8	106,426	115,280
		278,042	239,660
Current assets			
Trade receivables		60	387
Other receivables		7,183	6,957
Prepayments		15,322	13,994
Marketable securities	8	169,659	134,278
Cash and cash equivalents		495,047	584,517
		687,271	740,133
Total assets		965,313	979,793
Equity and liabilities			
Equity			
Share capital	9	7,228	7,217
Distributable equity		795,591	831,494
		802,819	838,711
Non-current liabilities			
Lease liabilities	10	89,568	85,116
Other payables		—	3,162
		89,568	88,278
Current liabilities			
Lease liabilities	10	6,913	6,859
Contract liabilities		254	363
Trade payables and accrued expenses		54,133	21,897
Other payables		11,253	23,384
Income taxes payable		373	301
		72,926	52,804
Total liabilities		162,494	141,082
Total equity and liabilities		965,313	979,793

Unaudited Condensed Consolidated Interim Statements of Changes in Equity

	Distributable Equity					Total
	Share Capital	Share Premium	Foreign Currency Translation Reserve	Share-based Payment Reserve	Accumulated Deficit	
	(EUR'000)					
Equity at January 1, 2021	7,217	1,728,747	(76)	133,101	(1,030,278)	838,711
Loss for the period	—	—	—	—	(62,792)	(62,792)
Other comprehensive income / (loss), net of tax	—	—	1,842	—	—	1,842
Total comprehensive income / (loss)	—	—	1,842	—	(62,792)	(60,950)
Transactions with Owners						
Share-based payment (Note 7)	—	—	—	23,076	—	23,076
Capital increase	11	1,971	—	—	—	1,982
Cost of capital increase	—	—	—	—	—	—
Equity at March 31, 2021	7,228	1,730,718	1,766	156,177	(1,093,070)	802,819

	Distributable Equity					Total
	Share Capital	Share Premium	Foreign Currency Translation Reserve	Share-based Payment Reserve	Accumulated Deficit	
	(EUR'000)					
Equity at January 1, 2020	6,443	1,122,097	(34)	79,931	(611,323)	597,114
Loss for the period	—	—	—	—	(63,317)	(63,317)
Other comprehensive income / (loss), net of tax	—	—	86	—	—	86
Total comprehensive income / (loss)	—	—	86	—	(63,317)	(63,231)
Transactions with Owners						
Share-based payment (Note 7)	—	—	—	14,949	—	14,949
Capital increase	—	—	—	—	—	—
Cost of capital increase	—	—	—	—	—	—
Equity at March 31, 2020	6,443	1,122,097	52	94,880	(674,640)	548,832

**Unaudited Condensed Consolidated Interim Cash Flow Statements for the
Three Months Ended March 31**

	Three Months Ended March 31,	
	2021	2020
	(EUR'000)	
Operating activities		
Net profit / (loss) for the period	(62,792)	(63,317)
Reversal of finance income	(34,430)	(11,773)
Reversal of finance expenses	869	447
Reversal of tax charge	(191)	(77)
Adjustments for non-cash items:		
Reversal of non-cash consideration relating to revenue	(577)	(1,202)
Reversal of share of profit / (loss) of associate	(28,106)	1,515
Share-based payment	23,076	14,949
Depreciation	3,603	1,993
Amortization	111	—
Changes in working capital:		
Receivables	110	797
Prepayments	(1,329)	(2,537)
Contract liabilities (deferred income)	(109)	(515)
Trade payables, accrued expenses and other payables	17,573	(8,872)
Cash flows generated from / (used in) operations	(82,192)	(68,592)
Interest received	975	1,455
Interest paid	(374)	(367)
Income taxes received / (paid)	(28)	718
Cash flows from / (used in) operating activities	(81,619)	(66,786)
Investing activities		
Investment in associate	(10,187)	—
Acquisition of property, plant and equipment	(4,025)	(6,141)
Development expenditures (software)	(530)	—
Purchase of marketable securities	(39,444)	—
Settlement of marketable securities	24,069	—
Cash flows from / (used in) investing activities	(30,117)	(6,141)
Financing activities		
Payment of lease liabilities	(1,962)	(1,117)
Capital increase	1,982	—
Cash flows from / (used in) financing activities	20	(1,117)
Increase / (decrease) in cash and cash equivalents	(111,716)	(74,044)
Cash and cash equivalents at January 1	584,517	598,106
Effect of exchange rate changes on balances held in foreign currencies	22,246	10,319
Cash and cash equivalents at March 31	495,047	534,381
Cash and cash equivalents include:		
Bank deposits	495,047	216,925
Short-term marketable securities	—	317,456
Cash and cash equivalents at March 31	495,047	534,381

Note 1—General Information

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

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

On February 2, 2015, the Company completed an initial public offering which resulted in the listing of American Depositary Shares, or 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 May 27, 2021.

Note 2—Summary of Significant Accounting Policies

Basis of Preparation

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

The accounting policies applied are consistent with those of the previous financial year. A description of our accounting policies is provided in the Accounting Policies section of the audited consolidated financial statements as of and for the year ended December 31, 2020.

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

New and Amended IFRS Standards Adopted by the Company

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

Note 3—Significant Accounting Judgements, Estimates and Assumptions

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 and estimates applied are based on historical experience and other factors that are relevant, and which are available at the reporting date. Uncertainty concerning judgements and estimates could result in outcomes, that require a material adjustment to assets and liabilities in future periods.

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

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

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

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

There have been no other changes to the application of significant accounting judgments, or estimation uncertainties regarding accounting estimates.

Warrant Compensation Costs

IFRS 2, “Share-Based Payment” requires an entity to reflect in its consolidated statement of profit or loss and financial position, the effects of share-based payment transactions. Warrant compensation costs are recognized over the vesting period as research and development costs or selling, general and administrative expenses, as appropriate, based on management’s best estimate of the number of warrants that will ultimately vest, which is subject to uncertainty.

Warrant compensation costs are measured according to the grant date fair values of the warrants granted. Estimating fair values requires the Company to apply generally accepted valuation models and apply these models consistently according to the terms and conditions of the specific warrant program. Under all warrant programs, the Black-Scholes option-pricing model has been applied to determine the fair value of warrants granted. Subjective judgements and assumptions, which are subject to estimation uncertainties, need to be exercised in determining the appropriate input to the valuation model. These inputs include expected volatility of the Company’s share price for a historic period equaling the expected lifetime of the warrants, reflecting the assumption that the historical volatility over a period similar to the life of the warrants is indicative of future trends. For the three months ended March 31, 2021, the expected volatility has been calculated using the Company’s own share price.

Note 4—Significant Events in the Reporting Period

Impact from COVID-19 pandemic

A novel strain of coronavirus, (“COVID-19”) was reported to have surfaced in Wuhan, China, in December 2019. Since then, COVID-19 has spread around the world into a pandemic, including into countries where we are operating, where we have planned or have ongoing clinical trials, and where we rely on third-parties to manufacture preclinical and clinical supplies, as well as commercial supply.

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

VISEN Pharmaceuticals Investment

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

Note 5—Revenue

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

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

	Three Months ended March 31,	
	2021	2020
	(EUR'000)	
Revenue from external customers		
Revenue from the rendering of services (recognized over time)	169	1,312
Sale of clinical supply (recognized at a point in time)	—	246
“Right-to-use” licenses (recognized at a point in time)	577	667
Total revenue (1)	746	2,225
Attributable to		
VISEN Pharmaceuticals	637	2,225
Other collaboration partners	109	—
Total revenue	746	2,225
Revenue by geographical location		
North America	686	667
China	60	1,558
Total revenue	746	2,225

- (1) For the three months ended March 31, 2021 and 2020, “Total revenue” includes recognition of previously deferred revenue/internal profit from associate of €577 thousand and €1,202 thousand, respectively.

Note 6—Segment Information

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

Note 7—Warrants and Share-based Payment**Share-based Payment**

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

Warrants are granted by the Company's Board of Directors in accordance with authorizations given to it by the shareholders of the Company. As of March 31, 2021, 10,944,778 warrants have been granted, of which 19,580 warrants have been cancelled, 4,255,638 warrants have been exercised, 2,168 warrants have expired without being exercised, and 557,450 warrants have been forfeited. As of March 31, 2021, the Company's Board of Directors was authorized to grant up to 682,509 additional warrants to employees, board members and select consultants without preemptive subscription rights for the shareholders of the Company. Each warrant carries the right to subscribe for one ordinary share of a nominal value of DKK 1. The exercise price is fixed at the fair market value of the Company's ordinary shares at the time of grant as determined by the Company's Board of Directors. The exercise prices of outstanding warrants under the Company's warrant programs range from €6.48 to €145.5 depending on the grant dates. Vested warrants may be exercised in two or four annual exercise periods. Apart from exercise prices and exercise periods, the programs are similar.

Warrant Activity

The following table specifies the warrant activity during the three months ended March 31, 2021.

	Total Warrants	Weighted Average Exercise Price EUR
Outstanding at January 1, 2021	6,148,004	69.97
Granted during the period	80,060	132.10
Exercised during the period	(78,993)	25.96
Forfeited during the period	(39,129)	108.59
Expired during the period	—	—
Outstanding at March 31, 2021	6,109,942	71.10
Vested at March 31, 2021	3,285,203	42.20

Warrant Compensation Costs

Warrant compensation costs are determined with a basis in the grant date fair value of the warrants granted and recognized over the vesting period as research and development costs or as selling, general and administrative expenses. For the three months ended March 31, 2021 and 2020, warrant compensation costs recognized in the interim statement of profit or loss was €23,076 thousand and €14,949 thousand, respectively.

Note 8—Marketable Securities

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

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

	March 31, 2021		December 31, 2020	
	Carrying amount	Fair value	Carrying amount	Fair value
	(EUR'000)			
Marketable securities				
U.S. Treasury bills	35,613	35,616	46,243	46,245
U.S. Government bonds	73,550	73,569	62,088	62,101
Commercial papers	11,081	11,081	10,583	10,581
Corporate bonds	141,781	141,656	121,282	121,234
Agency bonds	14,060	14,067	9,362	9,369
Total marketable securities	276,085	275,989	249,558	249,530
Classified based on maturity profile				
Non-current assets	106,426	106,361	115,280	115,277
Current assets	169,659	169,628	134,278	134,253
Total marketable securities	276,085	275,989	249,558	249,530
Specified by rate structure				
Fixed rate	210,947	210,859	175,757	175,732
Floating rate	18,443	18,433	16,975	16,972
Zero-coupon	46,695	46,697	56,826	58,826
Total marketable securities	276,085	275,989	249,558	249,530
Specified by investment grade credit rating				
Prime	8,028	8,026	7,716	7,714
High grade	148,813	148,844	142,339	142,352
Medium grade	119,244	119,119	99,503	99,464
Total marketable securities	276,085	275,989	249,558	249,530

The Company's marketable securities are all denominated in U.S. Dollars. At March 31, 2021, the portfolio has a weighted average duration of 5.8 and 17.2 months, for current and non-current positions, respectively. The entire portfolio has a weighted average duration of 10.2 months.

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

Note 9—Share Capital

The share capital of Ascendis Pharma A/S consists of 53,829,379 outstanding shares at a nominal value of DKK 1, all in the same share class.

Notes to the Unaudited Condensed Consolidated Interim Financial Statements

Note 10 —Lease Liabilities

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

Maturity analysis for lease liabilities recognized in the statements of financial position at March 31, 2021 is specified below.

	<u>< 1 year</u>	<u>1-5 years</u>	<u>>5 years</u>	<u>Total contractual cash-flows</u>	<u>Carrying amount</u>
	(EUR'000)				
March 31, 2021					
Lease liabilities	7,024	42,525	69,057	118,606	96,481

Note 11—Subsequent Events

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

ASCENDIS PHARMA A/S

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

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

Special Note Regarding Forward-Looking Statements

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

- the timing or likelihood of regulatory filings and approvals for our product candidates, including our expectations regarding approval of our Biologics License Application and Marketing Authorization Application for TransCon Growth Hormone, or TransCon hGH or lonapegsomatropin);
- 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 product candidates, if approved for commercial use;
- our expectations regarding the potential advantages of our 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, or 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 product candidates;
- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;
- the commercialization of our product candidates, if approved;

- our commercialization, marketing and manufacturing capabilities of our product candidates and associated devices;
- the implementation of our business model and strategic plans for our business, product candidates and technologies;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our financial performance;
- developments and projections relating to our competitors and our industry; and
- the effects on our business of the worldwide COVID-19 pandemic.

These forward-looking statements are based on senior management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this report may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section in our Annual Report on Form 20-F for the year ended December 31, 2020 — “Item 3.D. Risk Factors”. You are urged to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this report. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. Given these risks and uncertainties, you are cautioned not to rely on such forward-looking statements as predictions of future events.

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

Overview

We are applying our innovative TransCon technologies to build a leading, fully integrated biopharmaceutical company and develop a pipeline of product candidates with potential best-in-class profiles to address unmet medical needs. We currently have three product candidates in clinical development in rare endocrine diseases, one product candidate in clinical development in oncology, our second therapeutic area of focus, and we are advancing multiple preclinical candidates in oncology. We are also working to apply our TransCon technology platform in additional therapeutic areas to address unmet patient needs. We submitted regulatory applications for marketing approval for TransCon hGH (lonapegsomatropin) for the treatment of pediatric growth hormone disorder during 2020 in the United States and Europe, and we are building our commercial organization, starting with a focus in the United States.

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

We had a net loss of €62.8 million for the three months ended March 31, 2021, and a net loss of €419.0 million for the year ended December 31, 2020. Our total equity was €802.8 million as of March 31, 2021 compared to €838.7 million as of December 31, 2020.

TransCon Technologies

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

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

Lonapegsomatropin

Lonapegsomatropin is an investigational long-acting prodrug of somatropin (hGH) that is being developed for the treatment of GHD. It is designed to maintain the same mode of action as daily therapies by releasing the same growth hormone molecule, somatropin, as daily hGH therapy. Lonapegsomatropin is composed of an unmodified somatropin that is transiently bound to a carrier and proprietary linker.

We believe our once-weekly lonapegsomatropin has the same mode of action and distribution into key growth hormone-responsive tissues, such as brain, bone, muscle, liver and fat tissue, as the hGH administered from daily injections and endogenous growth hormone. We use daily growth hormone as an active comparator in our clinical studies, allowing us to directly compare the activity of lonapegsomatropin to daily growth hormone in an identical clinical setting.

Our phase 3 pediatric program for lonapegsomatropin consists of the heiGHt, fliGHt and enliGHten Trials. The heiGHt Trial was a randomized, open-label, active-controlled phase 3 registrational trial that enrolled 161 children with GHD who had not previously been treated. The fliGHt Trial was designed to evaluate lonapegsomatropin in subjects who were primarily treatment experienced with daily somatropin, although a subgroup of younger subjects were treatment-naïve. Nearly all subjects who completed the heiGHt or fliGHt Trials have enrolled in the open-label extension study, or the enliGHten Trial, which is designed to provide long-term safety data to support the regulatory submissions for lonapegsomatropin. We initiated the enliGHten Trial in 2017 as the first subjects began to roll over from the heiGHt Trial, and we have enrolled approximately 300 pediatric subjects. Data from enliGHten formed the long-term safety database supporting our Biologics License Application, or BLA, submission to the U.S. Food and Drug Administration, or FDA, for lonapegsomatropin for the treatment of pediatric GHD which occurred in June 2020, as well as submission of a Marketing Authorization Application, or MAA to the European Medicines Agency, or EMA, which occurred in September 2020. The PDUFA user fee goal date is set for June 25, 2021.

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

In September 2020, we filed a Clinical Trial Notification, or CTN, with the Pharmaceuticals and Medical Devices Agency, or PMDA in Japan, to initiate our phase 3 riGHt Trial of lonapegsomatropin for the treatment for 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 July 2020, the EMA adopted a decision agreeing with the positive opinion from the Paediatric Committee, on agreeing with the proposed Paediatric Investigation Plan, or PIP, for lonapegsomatropin. The PIP endorsed the lonapegsomatropin program as acceptable for assessment of safety and efficacy for the use of lonapegsomatropin as a treatment for GHD in children from six months to less than 18 years of age, mirroring the population covered by the studies conducted in the program.

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

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

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

TransCon Parathyroid Hormone

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

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

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

TransCon PTH is currently in phase 3 development as a treatment for adult HP. In September 2020, we submitted an amendment to our IND to initiate PaTHway, our global phase 3 clinical trial evaluating the safety, tolerability and efficacy of TransCon PTH in adults with HP following discussions with FDA and European regulatory authorities. The double-blind, placebo-controlled trial is expected to enroll approximately 76 subjects at sites in North America and Europe in order to obtain 68 evaluable subjects.

On May 10, 2021, we announced preliminary 58-week results from the continuing open-label extension, or OLE, portion of the PaTH Forward Trial, a global phase 2 trial evaluating the safety, tolerability, and efficacy of its investigational product candidate, TransCon PTH, in adult subjects with HP.

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

- 58 subjects continue in the open-label extension beyond 58 weeks as of May 7, 2021
- Continued treatment with TransCon PTH demonstrated that:
 - 91% of subjects were off standard of care therapy defined as no active vitamin D and £600 mg/day of calcium supplements
 - Urinary calcium maintained in the normal range
 - Bone markers trended towards the mid-normal levels
- Quality of life benefits measured by SF-36 continued within normal range
- TransCon PTH was well-tolerated at all doses administered
 - No treatment-related serious or severe adverse events occurred, and no treatment-emergent adverse events led to discontinuation of study drug
 - No change to the safety profile in the OLE portion of the study

In May 2021, we filed a CTN with the PDMA in Japan to initiate our phase 3 clinical trial of TransCon PTH in adult subjects with HP, the PaTHway Japan Trial.

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

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

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

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

TransCon C-Type Natriuretic Peptide

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

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

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.

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

TransCon Product Candidates within Oncology

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

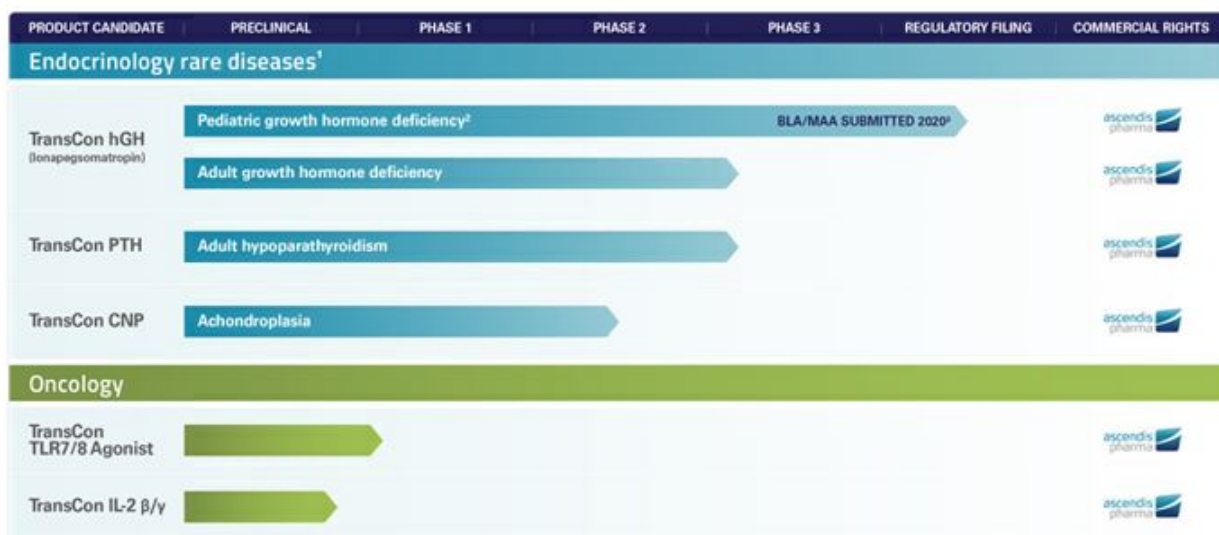
We are conducting preclinical studies within the field of oncology to explore multiple potential product candidates and evaluate systemic as well as localized delivery systems using our TransCon technology platform.

We are currently advancing two product candidates:

- TransCon TLR7/8 Agonist is designed for sustained release of TLR7/8 agonist, resiquimod, and intended for intratumoral administration. This product candidate is designed to provide potent activation of the innate immune system in the tumor and draining lymph nodes and to have low risk of systemic toxicity. In December 2020, we filed an IND with the U.S. Food and Drug Administration to initiate the clinical program of TransCon TLR7/8 Agonist with the transcendIT-101 Trial.
- TransCon IL-2 β/g, is designed for prolonged exposure of an IL-2 variant that selectively activates the IL-2Rβ/g, with minimal binding to IL-2Rα. This product candidate is designed to provide potent anti-tumor activity and to have reduced risk of toxicity, such as vascular leak syndrome.

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

TransCon Product Candidate Pipeline



1. Excludes rights granted to VISEN Pharmaceuticals in Greater China
2. In phase 3 development for pediatric growth hormone deficiency in Greater China through VISEN Pharmaceuticals
3. U.S. PDUFA June 25, 2021

Results of Operations

Impact from COVID-19 Pandemic

A novel strain of coronavirus, (“COVID-19”) was reported to have surfaced in Wuhan, China, in December 2019. Since then, COVID-19 has spread around the world into a pandemic, including into countries where we are operating, where we have planned or have ongoing clinical trials, and where we rely on third-parties to manufacture preclinical and clinical supplies, as well as commercial supply.

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

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

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

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

While COVID-19 did not have a significant negative impact on our business, we foresee elevated COVID-19 related risks in certain areas, including:

- In conducting our clinical trials, there is a risk that suppliers experience delays in providing necessary equipment, consumables and services, which potentially could cause temporary delays in clinical trial activities. In addition, there is a risk that patients will elect not to enroll in trials to limit their exposure to medical institutions, which could potentially have a negative impact on clinical trial timelines;
- Global demand for COVID-19 vaccines could result in contract manufacturers not having sufficient capacity to meet scheduled manufacturing. In addition, sourcing of certain types of raw materials, consumables and equipment could result in scheduled manufacturing being delayed or postponed;
- Travel restrictions and local outbreaks of COVID-19 could restrict authorities from performing site inspections in connection with their review procedures of marketing applications for TransCon hGH (longapegsomatropin), which could potentially delay the commercial launch; and
- Our commercial launch strategy could be negatively impacted by patients not being able to see their physicians, and similarly, our commercial team not being able to meet with physicians, which could both have a negative impact on the commercial launch strategy.

We monitor these risks closely, and work with relevant stakeholders to avoid 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 related to COVID-19 related risks, please refer to “Item 3D. Risk Factors”, set forth in our 2020 annual report on Form 20-F.

Comparison of the Three Months Ended March 31, 2021 and 2020 (unaudited):

	Three Months Ended March 31,	
	2021	2020
	(EUR'000)	
Revenue	746	2,225
Research and development costs	(88,149)	(57,515)
Selling, general and administrative expenses	(37,247)	(17,915)
Operating profit / (loss)	(124,650)	(73,205)
Share of profit / (loss) of associate	28,106	(1,515)
Finance income	34,430	11,773
Finance expenses	(869)	(447)
Profit / (loss) before tax	(62,983)	(63,394)
Tax on profit / (loss) for the period	191	77
Net profit / (loss) for the period	(62,792)	(63,317)

Revenue

Revenue for the three months ended March 31, 2021 was €0.7 million, a decrease of €1.5 million, compared to €2.2 million for the three months ended March 31, 2020, and primarily comprised sale of clinical supply, rendering of services, and recognition of internal profit deferred from November 2018 when we entered into the collaboration with VISEN. The decrease was due to a lower amount of license revenue being recognized, as well as lower sale of clinical supply and services to VISEN compared to the same period last year.

Research and Development Costs

Research and development costs were €88.1 million for the three months ended March 31, 2021, an increase of €30.6 million, or 53%, compared to €57.5 million for the three months ended March 31, 2020.

External development costs related to lonapegsomatropin increased by €10.1 million compared to the same period last year, reflecting higher costs for manufacturing of product supply, but also reflecting higher costs for the ongoing clinical trials.

External development costs related to TransCon PTH increased by €1.8 million, primarily reflecting increased costs related to manufacturing of validation batches, device development, and increasing costs for clinical trials and clinical supplies, compared to the same period last year.

External development costs related to TransCon CNP increased by €5.9 million, primarily reflecting an increase in clinical trial costs and clinical supplies, but also increasing manufacturing costs.

External development costs related to our oncology product candidates, primarily TransCon TLR7/8 Agonist and TransCon IL-2 β /g increased by €5.5 million, reflecting an increase in manufacturing costs and preclinical costs as these product candidates progress through the early development stages and into manufacturing and clinical trials.

Other research and development costs increased by €7.3 million, primarily driven by an increase in personnel costs of €5.0 million and non-cash share-based payment of €5.3 million due to a higher number of employees in research and development functions. Other costs allocated to research and development functions decreased by a total of €3.0 million, primarily relating to IT, travel costs, and professional fees.

Research and development costs included non-cash share-based payment of €14.2 million for the three months ended March 31, 2021, compared to €8.9 million for the three months ended March 31, 2020.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were €37.2 million for the three months ended March 31, 2021, an increase of €19.3 million, or 108%, compared to €17.9 million for the three months ended March 31, 2020. The higher expenses were primarily due to an increase in personnel costs of €4.8 million and non-cash share-based payment of €2.8 million for additional commercial and administrative personnel. Other costs allocated to selling, general and administrative functions increased by a total of €11.7 million, primarily reflecting increasing IT costs, including the implementation of a new ERP-system of €5.1 million, insurance costs of €2.2 million, professional fees of €1.6 million, and costs related to building our commercial business of €1.8 million.

Selling, general and administrative expenses included non-cash share-based payment of €8.9 million for the three months ended March 31, 2021, compared to €6.1 million for the three months ended March 31, 2020.

Net Profit / (Loss) of Associate

Net profit of associate was €28.1 million for the three months ended March 31, 2021, compared to a net loss of €1.5 million for the three months ended March 31, 2020.

For the three months ended March 31, 2021, the net profit of associate comprises a non-cash gain of €42.3 million as a result of the Series B financing in VISEN on January 8, 2021, and the Company's share of loss of €14.2 million. The Series B financing has not changed the Company's accounting treatment of VISEN.

Finance Income and Finance Expenses

Finance income was €34.4 million for the three months ended March 31, 2021 compared to €11.8 million for the three months ended March 31, 2020. Finance expenses were €0.9 million for the three months ended March 31, 2021 compared to €0.4 million for the same period in 2020. As we hold positions of marketable securities and cash and cash equivalents in U.S. Dollar, we are affected by exchange rate fluctuations when reporting our financial results in Euro. For the three months ended March 31, 2021, as well as for the same period last year, we recognized net exchange rate gains when reporting our U.S. Dollar positions in Euro, reflecting positive exchange rate fluctuations.

We did not have any interest-bearing debt for any of the periods presented. However, IFRS 16, "Leases", requires interest expenses to be recognized on lease liabilities.

Tax for the Period

Tax for the three months ended March 31, 2021 was a net tax credit of €0.2 million compared to a net tax credit of €0.1 million for the three months ended March 31, 2020. Taxes for the three months ended March 31, 2021 comprised an estimated tax credit of €0.2 million in the group of Danish companies and a tax credit of €0.1 million in our U.S. subsidiaries, partly offset by a tax provision of €0.1 million in our German subsidiary.

Liquidity and Capital Resources

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

As of March 31, 2021, these amounted to €771.1 million, and are specified as follows:

	<u>Carrying amount</u>	<u>Fair value</u>
	(EUR'000)	
March 31, 2021		
Liquidity and capital resources		
Marketable securities	276,085	275,989
Cash and cash equivalents	495,047	495,047
Total liquidity and capital resources	<u>771,132</u>	<u>771,036</u>
Classification in consolidated statement of financial position		
Non-current assets	106,426	106,361
Current assets	664,706	664,675
Total liquidity and capital resources	<u>771,132</u>	<u>771,036</u>

Marketable securities have a weighted average duration of 5.8 and 17.2 months, for current (i.e., those maturing within twelve months after the reporting date) and non-current positions, respectively. The entire portfolio of marketable securities (current and non-current) has a weighted average duration of 10.2 months.

We have historically funded our operations primarily through issuance of preference shares, ordinary shares, including our initial public offering, follow-on offerings and exercise of warrants, convertible debt securities, and payments to us 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); and
- In 2020, with net proceeds of \$654.6 million (or €580.5 million).

Our expenditures are primarily related to research and development activities and general and administrative activities to support research and development, as well as activities for building our sales and marketing capabilities.

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

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities as of March 31, 2021, will be sufficient to meet our projected cash requirements for at least 12 months from the date of this report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including, but not limited to:

- the manufacturing, selling and marketing costs associated with product candidates, including the cost and timing of building our sales and marketing capabilities;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the sales price and the availability of adequate third-party coverage and reimbursement for our product candidates;

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to collect payments which are due to us from collaboration partners (if any), which in turn is impacted by the financial standing of any such collaboration partners;
- the progress, timing, scope, results and costs of our preclinical studies and clinical trials and manufacturing activities for our product candidates that have not been licensed, including the ability to enroll patients in a timely manner for clinical trials;
- the time and cost necessary to obtain regulatory approvals for our product candidates that have not been licensed and the costs of post-marketing studies that could be required by regulatory authorities;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the number and scope of preclinical and discovery programs that we decide to pursue or initiate;
- the potential acquisition and in-licensing of other technologies, products or assets;
- the time and cost necessary to respond to technological and market developments, including further development of our TransCon technologies;
- the achievement of development, regulatory and commercial milestones resulting in the payment to us from collaboration partners of contractual milestone payments and the timing of receipt of such payments, if any;
- our progress in the successful commercialization and co-promotion of our most advanced product candidates 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 our cash flows for each of the unaudited three month periods ended March 31, 2021 and 2020:

	Three Months Ended	
	March 31,	
	2021	2020
	(EUR'000)	
Cash flows from / (used in) operating activities	(81,619)	(66,786)
Cash flows from / (used in) investing activities	(30,117)	(6,141)
Cash flows from / (used in) financing activities	20	(1,117)
Net increase / (decrease) in cash and cash equivalents	(111,716)	(74,044)

Cash Flows from / (Used in) Operating Activities

Net cash used in operating activities for the three months ended March 31, 2021 was €81.6 million compared to €66.8 million for the three months ended March 31, 2020. The net loss for the three months ended March 31, 2021 of €62.8 million included non-cash charges of €26.8 million, comprising share-based payment, depreciation and amortization, and non-cash net income, including non-cash revenue, net financial income and taxes, of €61.9 million. The net change in working capital contributed positively to cash flows by €16.3 million, primarily due to a net increase in trade payables, accrued expenses and other payables of €17.6 million, an increase in prepayments and receivables of €1.2 million, and a decrease in deferred income of €0.1 million.

Net cash used in operating activities for the three months ended March 31, 2020 was €66.8 million. The net loss for the three months ended March 31, 2020 of €63.3 million included non-cash charges of €16.9 million, comprising share-based payment and depreciation, and non-cash net income, including net financial income and taxes, of €9.3 million. The net change in working capital contributed negatively to cash flows by €11.1 million, primarily due to a net decrease in trade payables and other payables of €8.9 million, an increase in receivables and prepayments of €1.7 million, and a decrease in deferred income of €0.5 million.

Cash Flows from / (Used in) Investing Activities

Cash flows used in investing activities for the three months ended March 31, 2021 of €30.1 million were related to the acquisition of marketable securities of €39.4 million and the settlement of marketable securities of €24.1 million, to Series B investment in VISEN of €10.2 million, to the acquisition of property, plant and equipment of €4.0 million, primarily related to leasehold improvements and equipment for use in the United States, and to the acquisition of software of €0.5 million.

Cash flows used in investing activities for the three months ended March 31, 2020 of €6.1 million were related to the acquisition of property, plant and equipment, primarily related to our oncology laboratory facilities in the United States, and for use in the laboratories of our German facility.

Cash Flows from / (Used in) Financing Activities

Cash flows from financing activities for the three months ended March 31, 2021 of €20 thousand were comprised of €2.0 million in net proceeds from warrant exercises in March 2021, offset by payments on lease liabilities of €2.0 million.

Cash flows used in financing activities for the three months ended March 31, 2020 of €1.1 million were comprised of payments on lease liabilities.

Off-balance Sheet Arrangements

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

Qualitative Disclosures about Market Risk

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

Foreign Currency Risk

We are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the U.S. Dollar, the British Pound and the Danish Krone. We have received payments in U.S. Dollars under our collaborations, and the proceeds from our series D financing in November 2014, our initial public offering in February 2015, and our follow-on offerings, the latest being in July 2020, were in U.S. Dollars. We seek to minimize our exchange rate risk by maintaining cash positions in the currencies in which we expect to incur the majority of our future expenses and we make payments from those positions.

Interest Rate Risk

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

Credit Risk

We have adopted an investment policy with the primary purpose of preserving capital, fulfilling our liquidity needs and diversifying the risks associated with cash, cash equivalents and marketable securities. Our investment policy establishes minimum ratings for institutions with which the Company holds 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 counterparty is considered to be low. Our exposure to credit risk primarily relates to cash, cash equivalents, and marketable securities. The credit risk on our bank deposits is limited because the counterparties, holding significant deposits, are banks with high credit rating (minimum A3/A-) assigned by international credit ratings agencies. The banks are reviewed on a regular basis and deposits may be transferred during the year to mitigate credit risk. On each reporting date, we consider the risk of expected credit loss on bank deposits, including the hypothetical impact arising from the probability of default, which is considered in conjunction with the expected loss caused by default by banks with similar credit ratings and attributes. In line with previous periods, this assessment did not reveal a material impairment loss, and accordingly no provision for expected credit loss has been recognized.

Since March 2020, in order to mitigate the concentration of credit risks on bank deposits and to preserve capital, a portion of our bank deposits have been placed into primarily U.S. government bonds treasury bills, corporate bonds and commercial papers. Our investment policy, approved by the Board of Directors, only allows investment in marketable securities having investment grade credit ratings, assigned by international credit rating agencies. Accordingly, the risk and probability of default is low. The risk of expected credit loss on marketable securities has been considered, including the hypothetical impact arising from the probability of default, which is considered in conjunction with the expected loss caused by default on securities with similar credit ratings and attributes. This assessment did not reveal a material expected credit loss, and accordingly no provision for expected credit loss has been recognized.

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



Ascendis Pharma A/S Reports First Quarter 2021 Financial Results

- *Pre-launch activities continue in preparation for a potential FDA approval of TransCon™ hGH (lonapegsomatropin) for pediatric growth hormone deficiency; PDUFA date of June 25, 2021 –*
- *58-week data from PaTH Forward demonstrated durable benefit of TransCon PTH signifying potential as a hormone replacement therapy for patients with hypoparathyroidism –*
- *First-in-human dosing for Ascendis Oncology portfolio with the transcendIT-101 clinical trial moving forward –*
- *Conference call today at 4:30 p.m. Eastern Time –*

COPENHAGEN, Denmark, May 27, 2021 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND), a biopharmaceutical company that utilizes its innovative TransCon™ technologies to create product candidates that address unmet medical needs, today announced financial results for the first quarter ended March 31, 2021.

“With potential U.S. FDA approval for TransCon hGH now less than a month away, we believe we are one step closer to fulfilling our Vision 3x3 to build a leading biopharma company. Guided by our values of patients, science and passion, we have built a pipeline of three differentiated endocrinology rare disease product candidates by applying our TransCon technology to clinically validated parent drugs and/or targets. Each candidate targeting substantial unmet medical needs in large markets where we have the potential to become the market leader. We plan to replicate that success in oncology where we have dosed our first patients this past quarter in the transcendIT-101 Trial of TransCon TLR7/8 Agonist and expect to file an IND or similar for our second oncology product candidate TransCon IL-2 β/g in Q3 2021. Improving patient lives is the driving force behind our dedicated employees,” said Jan Mikkelsen, Ascendis Pharma’s President and Chief Executive Officer.

Company Highlights & Progress

- TransCon hGH (lonapegsomatropin)
 - Continued pre-launch commercial activities in preparation of the PDUFA date on June 25, 2021 and an expected subsequent commercial launch of lonapegsomatropin in the United States in the third quarter of 2021 for the treatment of pediatric patients with growth hormone deficiency (GHD). All FDA information requests relating to our BLA for TransCon hGH for the treatment of pediatric GHD have been responded to with no questions currently outstanding.
 - European Commission decision on the company’s Marketing Authorisation Application (MAA) is anticipated in the fourth quarter of 2021 for the treatment of pediatric patients with GHD.
 - A recent study published online in the Journal of Managed Care & Specialty Pharmacy¹ and presented at ENDO 2021 highlighted the economic burden of GHD in the U.S. pediatric population. The study demonstrated that pediatric GHD is a significant healthcare burden, and many patients remain untreated or undertreated with high rates of non-adherence (70-80%).
 - Continued execution in the ongoing foresiGHt Trial, a global phase 3 trial in adults with GHD, complete enrollment expected by late 2021 or early 2022.
 - Continued execution in the ongoing riGHt Trial, a Japanese phase 3 trial for pediatric GHD.
 - In Greater China, VISEN Pharmaceuticals completed the patient enrollment of 154 treatment-naïve, prepubertal children for the ongoing phase 3 pivotal trial of lonapegsomatropin in patients with pediatric GHD.

- TransCon PTH
 - Announced preliminary 58-week results from the continuing open-label extension (OLE) portion of the PaTH Forward Trial, a global phase 2 trial evaluating the safety, tolerability, and efficacy of its investigational product candidate TransCon PTH in adult subjects with hypoparathyroidism (HP). The results demonstrated that TransCon PTH was well tolerated at all doses administered and provided durable benefit in adults with HP. As of May 25, 2021, 58 out of the 59 randomized subjects continue in the OLE portion of the phase 2 PaTH Forward Trial.
 - Filed a Clinical Trial Notification with the Pharmaceuticals and Medical Devices Agency in Japan to initiate the company's phase 3 clinical trial of TransCon PTH in adult subjects with HP, the PaTHway Japan Trial.
 - Continued execution in the ongoing North American and European phase 3 PaTHway Trial in adults with HP with topline results expected in the fourth quarter of 2021.
- TransCon CNP
 - Continued execution in the ongoing phase 2 ACcomplish Trial and ACcomplish China Trial to evaluate the safety and efficacy of TransCon CNP in children ages two to ten with achondroplasia.
 - On track for clinical program update on both randomized, double-blind, placebo-controlled trials expected in the fourth quarter of 2021.
- TransCon TLR7/8 Agonist
 - Continued execution in the ongoing phase 1/2 trial, transcendIT-101.
- TransCon IL-2 β /g
 - IND filing or similar planned in the third quarter of 2021.
- Ended the first quarter of 2021 with cash, cash equivalents and marketable securities totaling €771.1 million.

First Quarter 2021 Financial Results

For the first quarter, Ascendis Pharma reported a net loss of €62.8 million, or €1.17 per share (basic and diluted) compared to a net loss of €63.3 million, or €1.32 per share (basic and diluted) for the same period in 2020.

Revenue for the first quarter was €0.7 million compared to €2.2 million in the same quarter of 2020. The decrease was due primarily to a lower amount of license revenue being recognized, as well as lower sale of clinical supply and services to VISEN compared to the same period the prior year.

Research and development (R&D) costs for the first quarter were €88.1 million compared to €57.5 million during the same period in 2020. Higher R&D costs in 2021 reflect an increase in personnel-related costs and continued progress in development of the company's product candidates.

Selling, general and administrative expenses for the first quarter were €37.2 million compared to €17.9 million during the same period in 2020. The increase is primarily due to higher personnel-related costs, continued build out of the company's commercial capabilities, and a change in expense reallocation of shared services.

Net profit of associate for the first quarter was €28.1 million compared to a net loss of €1.5 million in the same quarter of 2020. Net profit of associate for the first quarter included a non-cash gain of €42.3 million as a result of the Series B financing in VISEN on January 8, 2021, partly offset by our share of VISEN's net loss for the first quarter of €14.2 million.

As of March 31, 2021, Ascendis Pharma had cash, cash equivalents and marketable securities of €771.1 million compared to €834.1 million as of December 31, 2020. As of March 31, 2021, Ascendis Pharma had 53,829,379 ordinary shares outstanding.

Conference Call and Webcast Information

Date	Thursday, May 27, 2021
Time	4:30 p.m. Eastern Time/1:30 p.m. Pacific Time
Dial In (U.S.)	844-290-3904
Dial In (International)	574-990-1036
Access Code	4986247

A live webcast of the conference call will be available on the Investors and News section of the Ascendis Pharma website at www.ascendispharma.com. A webcast replay will be available on this website shortly after conclusion of the event for 30 days.

About Ascendis Pharma's Pipeline

Ascendis Pharma currently has three product candidates in clinical development in rare endocrine diseases and one oncology product candidate in clinical development:

- TransCon hGH (lonapegsomatropin), an investigational long-acting prodrug of somatropin (human growth hormone or hGH) that releases somatropin with the identical amino acid sequence and size as daily growth hormone, is designed as a once-weekly treatment for GHD and is currently under regulatory review for pediatric GHD by the U.S. Food and Drug Administration and the European Medicines Agency.
- TransCon PTH, an investigational long-acting prodrug of parathyroid hormone (PTH) in phase 3 development as a once-daily replacement therapy for adults with hypoparathyroidism designed to replace PTH at physiologic levels for 24 hours, and address both short-term symptoms and long-term complications of the disease.
- TransCon CNP, an investigational long-acting prodrug of C-type natriuretic peptide (CNP) in phase 2 development as a therapy for children with achondroplasia (ACH), the most common form of dwarfism, for which there is no FDA-approved treatment. TransCon CNP is designed to provide continuous exposure of CNP at safe, therapeutic levels via a single, weekly subcutaneous dose.
- TransCon TLR7/8 Agonist is an investigational long-acting prodrug of resiquimod, a small molecule agonist of Toll-like receptors (TLR) 7 and 8. Administered as an intratumoral injection, TransCon TLR7/8 Agonist is designed to provide sustained activation of intratumoral antigen presenting cells driving tumor antigen presentation and induction of immune stimulatory cytokines in the tumor.
- TransCon IL-2 β /g is an investigational long-acting prodrug of IL-2 β /g designed for optimized IL-2R β /g bias and potency, combined with low Cmax and long exposure.

About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative platform technology to build a leading, fully integrated biopharma company focused on making a meaningful difference in patients' lives. Guided by its core values of patients, science and passion, the company utilizes its TransCon technologies to create new and potentially best-in-class therapies.

Ascendis Pharma currently has a pipeline of three independent endocrinology rare disease product candidates and one oncology product candidate in clinical development. The company continues to expand into additional therapeutic areas to address unmet patient needs.

Ascendis is headquartered in Copenhagen, Denmark, with additional facilities in Heidelberg and Berlin, Germany, in Palo Alto and Redwood City, California, and in Princeton, New Jersey.

Please visit www.ascendispharma.com (for global information) or www.ascendispharma.us (for U.S. information).

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding Ascendis' future operations, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to (i) Ascendis' expectations regarding the potential commercial launch of lonapegsomatropin, (ii) Ascendis' corporate goals and Vision 3x3, (iii) Ascendis' PDUFA date for its Biologics License Application for lonapegsomatropin, (iv) Ascendis' planned IND or similar submission for TransCon IL-2 β /g in Q3 2021, (v) Ascendis' ability to apply its platform technology to build a leading, fully integrated biopharma company, (vi) Ascendis' product pipeline and expansion into additional therapeutic areas and (vii) Ascendis' expectations regarding its ability to utilize its TransCon technologies to create new and potentially best-in-class therapies. Ascendis may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Ascendis makes, including the following: unforeseen safety or efficacy results in its oncology programs, lonapegsomatropin, TransCon PTH and TransCon CNP or other development programs; unforeseen expenses related to the development and potential commercialization of its oncology programs, lonapegsomatropin, TransCon PTH and TransCon CNP or other development programs, selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its oncology programs, lonapegsomatropin, TransCon PTH and TransCon CNP or other development programs related to manufacturing, regulatory requirements, speed of patient recruitment or other unforeseen delays; dependence on third party manufacturers to supply study drug for planned clinical studies; Ascendis' ability to obtain additional funding, if needed, to support its business activities and the effects on its business of the worldwide COVID-19 pandemic. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Ascendis' business in general, see Ascendis' Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC) on March 10, 2021 and Ascendis' current and future reports filed with, or submitted to, the SEC. Forward-looking statements do not reflect the potential impact of any future in-licensing, collaborations, acquisitions, mergers, dispositions, joint ventures, or investments that Ascendis may enter into or make. Ascendis does not assume any obligation to update any forward-looking statements, except as required by law.

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¹ Kaplowitz P, et al. Economic burden of growth hormone deficiency in a US pediatric population. *J Manag Care Spec Pharm*. 2021 Apr 24:1-11. doi: 10.18553/jmcp.2021.21030.